ISSUES RELATING TO MEDICARE'S COVERAGE POLICY

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON WAYS AND MEANS
HOUSE OF REPRESENTATIVES

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ISSUES RELATING TO MEDICARE'S COVERAGE POLICY

THURSDAY, APRIL 17, 1997

HOUSE OF REPRESENTATIVES,
COMMITTEE ON WAYS AND MEANS,
SUBCOMMITTEE ON HEALTH,
Washington, DC.

The Subcommittee met, pursuant to notice, at 1:09 p.m., in room 1100, Longworth House Office Building, Hon. Bill Thomas (Chairman of the Subcommittee) presiding.

[The advisory announcing the hearing follows:]

ADVISORY

FROM THE COMMITTEE ON WAYS AND MEANS

SUBCOMMITTEE ON HEALTH

FOR IMMEDIATE RELEASE
April 10, 1997
No. HL–10

CONTACT: (202) 225–3943

Thomas Announces Hearing on Issues Relating to Medicare's Coverage Policy

Congressman Bill Thomas (R–CA), Chairman, Subcommittee on Health of the Committee on Ways and Means, today announced that the Subcommittee will hold a hearing on issues relating to Medicare's coverage policy. The hearing will take place on Thursday, April 17, 1997, in the main Committee hearing room, 1100 Longworth House Office Building, beginning at 1:00 p.m.

In view of the limited time available to hear witnesses, oral testimony at this hearing will be from invited witnesses only. However, any individual or organization not scheduled for an oral appearance may submit a written statement for consideration by the Committee and for inclusion in the printed record of the hearing.

BACKGROUND:

Under the Social Security Act, Medicare explicitly covers broad categories of benefits, but in general, does not specify coverage for individual items and services. As such, the Secretary of Health and Human Services has discretion to make coverage decisions for items and servicesdetermined to be "reasonable and necessary" for the diagnosis and treatment of an illness or injury, or to improve the function of a malformed body part. Historically, the Health Care Financing Administration (HCFA) has interpreted the definition of reasonable and necessary to be "safe and effective" by acceptable clinical evidence. In evaluating coverage decisions, HCFA considers several factors, including the potential for widespread use in medical practice, the level of disagreement about the technology's safety and effectiveness, and the variation among contractor decisions.

In 1989, HCFA issued a proposed regulation on Medicare coverage decisions that included in the criteria an analysis of "cost-effectiveness." Last year, HCFA indicated that it would issue final regulations on the 1989 proposed regulations. However, because of concerns raised about the seven-year gap between the proposed and final regulations, and serious concern that the use of cost-effectiveness as a criteria could preclude beneficiaries from receiving life-saving services, HCFA decided that it would no longer pursue its Medicare coverage policy through the regulatory process at this time. It is clear that questions remain about HCFA's current decision-making process and the impact of this process on patient access to advanced medical technology.

In announcing the hearing, Chairman Thomas stated: "With constant advances in medical sciences and changing practice patterns, we need to make sure Medicare beneficiaries have the most up-to-date and fair system for bringing state-of-the-art medicine to beneficiaries as quickly as possible. Beneficiaries deserve a system that encourages medical innovation while ensuring the safety of patients."

FOCUS OF THE HEARING:

The hearing will focus on Medicare's current coverage policy, beneficiary access to new medical technologies and procedures, the appropriate relationship among Federal agencies in Medicare coverage decision-making, interactions between coverage decisions and the private sector, and the impact of coverage decisions on beneficiary selection of Medicare managed-care plans.

DETAILS FOR SUBMISSION OF WRITTEN COMMENTS:

Any person or organization wishing to submit a written statement for the printed record of the hearing should submit at least six (6) copies of their statement and a 3.5-inch diskette in WordPerfect or ASCII format, with their address and date of hearing noted, by the close of business, Thursday, May 1, 1997, to A.L. Singleton, Chief of Staff, Committee on Ways and Means, U.S. House of Representatives, 1102 Longworth House Office Building, Washington, D.C. 20515. If those filing written statements wish to have their statements distributed to the press and interested public at the hearing, they may deliver 200 additional copies for this purpose to the Subcommittee on Health office, room 1136 Longworth House Office Building, at least one hour before the hearing begins.

FORMATTING REQUIREMENTS:

Each statement presented for printing to the Committee by a witness, any written statement or exhibit submitted for the printed record or any written comments in response to a request for written comments must conform to the guidelines listed below. Any statement or exhibit not in compliance with these guidelines will not be printed, but will be maintained in the Committee files for review and use by the Committee.

1. All statements and any accompanying exhibits for printing must be typed in single space on legal-size paper and may not exceed a total of 10 pages including attachments. At the same time written statements are submitted to the Committee, witnesses are now requested to submit their statements on a 3.5-inch diskette in WordPerfect or ASCII format.

2. Copies of whole documents submitted as exhibit material will not be accepted for printing. Instead, exhibit material should be referenced and quoted or paraphrased. All exhibit material not meeting these specifications will be maintained in the Committee files for review and use by the Committee.

3. A witness appearing at a public hearing, or submitting a statement for the record of a public hearing, or submitting written comments in response to a published request for comments by the Committee, must include on his statement or submission a list of all clients, persons, or organizations on whose behalf the witness appears.

4. A supplemental sheet must accompany each statement listing the name, full address, a telephone number where the witness or the designated representative may be reached and a topical outline or summary of the comments and recommendations in the full statement. This supplemental sheet will not be included in the printed record.

The above restrictions and limitations apply only to material being submitted for printing. Statements and exhibits or supplementary material submitted solely for distribution to the Members, the press and the public during the course of a public hearing may be submitted in other forms.

Note: All Committee advisories and news releases are available on the World Wide Web at 'http://www.house.gov/ways_means/'.

The Committee seeks to make its facilities accessible to persons with disabilities. If you are in need of special accommodations, please call 202–225–1721 or 202–225–1904 TTD/TTY in advance of the event (four business days notice is requested). Questions with regard to special accommodation needs in general (including availability of Committee materials in alternative formats) may be directed to the Committee as noted above.

Chairman THOMAS. The Subcommittee will come to order.

Today's hearing will focus on Medicare's decisionmaking process for the coverage of medical services and treatments and the effects of this process on the medical care beneficiaries receive.

The Medicare statute specifies broad categories of services to be covered by Medicare. The HCFA, Health Care Financing Administration, has broad discretion under Medicare to make coverage decisions based on services and treatments determined to be medically necessary. Since the inception of Medicare, HCFA has used this authority to define coverage for everything from simple diagnostic tests to major organ transplants.

Medicare's current coverage policy was designed to respond in a decentralized manner to the time requirements of getting up and running and addressing the needs of a fee-for-service system in the sixties. As medical technologies develop and become increasingly complex and integrated, HCFA has had difficulty responding to coverage decisions in a timely and consistent manner, often affecting patient access to new technologies and related procedures.

Back in 1989, HCFA issued a proposed regulation on its coverage policy for Medicare, in part to address these issues. Under the proposed regulation, "cost effectiveness" would have been included as a coverage criteria. However, because of its controversial nature, HCFA never followed through—or for whatever other reason may have been the reason—HCFA never followed through with the final regulation.

Then just last year, 1996, HCFA dusted off the 1989 regulation and indicated to me, at least, that they were going to issue it as a final regulation. I did not support HCFA's decision to issue it as a final regulation because of what I consider to be a significant gap in time between the proposed and then the final regulations, a time gap that may not have been as critical in different periods but absolutely critical in the late eighties and early to midnineties.

Because I believed and continue to believe that this is an issue of critical importance to Medicare beneficiaries, we need a full public airing of the issue. We do need to move forward toward a new coverage policy which allows for flexibility and creates a clear standard that is consistent and timely. We should establish this new coverage policy with full public comment, since there are no clear guidelines at this time.

Seniors should have timely access to the constantly evolving, innovative improvements in medical technology. Hopefully, today's hearing will examine who should make the decisions about what is medically necessary, what standards should be used, and what is the best process for how conflicts should be resolved in a world of limited resources and unlimited demand.

I am reminded of my friend from Louisiana's admonition that people will consume as much health care as other people are willing to pay for, and in certain contexts, this certainly occurs.

At this time, I would like to submit for the record a written statement by our colleague from Minnesota, Mr. Ramstad, who could not be with us today. Mr. Ramstad has examined this issue closely and has provided valuable insight on issues related to bene-

ficiary access to medical technology. Without objection, his written statement will be made a part of the record.

[The prepared statement follows:]

Statement of Jim Ramstad, a Representative in Congress from the State of Minnesota

Mr. Chairman, thank you for calling this important hearing today to discuss Medicare's coverage policy.

I am looking forward to the testimony of Dr. Joel Cooper, chairman of thoracic surgery at the Washington University School of Medicine.

Dr. Cooper will be speaking on an issue that a few of my colleagues and I are deeply concerned about, an issue that we asked the Subcommittee to address—and we appreciate your including this topic in your hearing today.

I am referring to the Health Care Financing Administration's (HCFA) decision last year not to extend Medicare coverage for lung volume reduction surgery (LVRS).

Since this decision was made, HCFA and the National Institutes of Health (NIH) have called for a national multicenter randomized controlled trial study comparing LVRS with current medical treatments. The proposed 7-year study would include approximately 2,580 Medicare patients. While some patients in the study would receive LVRS, some would receive other treatments and procedures. Additionally, Medicare would not pay for LVRS for any patients treated outside of the study, despite the fact some private insurers do cover the procedures.

Because many in the medical community believe LVRS is a safe and effective treatment for certain patients with end-stage emphysema, my colleagues and I are concerned that the decision not to extend Medicare coverage for the procedure could negatively affect the lives of thousands of older Americans who suffer from this disease.

The proposed 7-year study of LVRS also places a cap on the number of medical centers eligible to particpate in the study and limits Medicare reimbursement to only a small number of patients at those centers to receive LVRS. Clearly, patient access to the LVRS procedure is severely restricted.

It is reasonable to gather and analyze data on patients who have received LVRS in order to determine the long-term efficacy and mortality associated with the procedure. It also seems reasonable for HCFA to limit reimbursement for the procedure to those patients who meet appropriate selection criteria and to medical centers that meet strict participation criteria. However, the decision to limit Medicare reimbursement to only those patients participating in the randomized study has created significant controversy with patients and within the medical community.

Because this situation raises important ethical and quality of care concerns, I would like to thank you again, Mr. Chairman, for calling this hearing. I look forward to the testimony of today's witnesses and learning more about Medicare's coverage policy for all items and services.

Chairman THOMAS. The gentleman from California.

Mr. STARK. Mr. Chairman, as I indicated to you, I was unsure about the direction of today's hearings, but I gather from your opening statement a flavor that I think makes me understand it better. I had a question for Mr. Vladeck, but it would serve as an opening statement and, I think, fits in with what you are talking about.

It suggests that the public trusts institutions less and less. They do not trust government much. They trust HMOs less and their doctors less. As budget pressures grow, there are going to be more rationing questions. We are hearing about them every day. Why was this denied? Why was that denied? I gather we will get into some of that today.

You mentioned that we may wind up missing OTA or some other independent group that can make some of these technical or professional decisions for us. Should we be thinking about either adding

this teaching responsibility to several of the boards that now advise us, whether it is PhysPRC, ProPAC, Congressional Research Service, GAO, or should we be thinking again about setting up a new medical scientific commission? We are going to, sooner or later, have some outcomes research. It will probably take 4 or 5 years to get enough of a data base for us to use it much, but then, how will that get used? We do not have the expertise or the resources to make that decision, and maybe that is something the witnesses can help us with as we go along today. How ought we get this empirical advice that would help us?

So I look forward to the witnesses and the Chair's comments this morning.

Chairman THOMAS. I thank the gentleman. Sometimes we are not limited by the advice we get. It is the attempt to evaluate it that is the difficult part.

Our first witnesses today, and it is nice to have the Administrator of the Health Care Financing Administration, Bruce Vladeck, with us again. With him is Dr. John Eisenberg, who is the Administrator of the Agency for Health Care Policy and Research, reasonably alive and well after the last congressional session, and Dr. Claude Lenfant, who is the Director of the National Heart, Lung, and Blood Institute, National Institutes of Health.

If you have any written statements, they will be made a part of the record and you may proceed to inform us for as much time as you believe is necessary, Mr. Vladeck, I would say, and the others are probably on a little tighter leash.

STATEMENT OF HON. BRUCE C. VLADECK, ADMINISTRATOR, HEALTH CARE FINANCING ADMINISTRATION

Mr. VLADECK. Thank you very much, Mr. Chairman. It is always a pleasure to be here, Mr. Stark and Mr. Houghton.

Today, it is a particular pleasure to be accompanied by my distinguished colleagues, Dr. Eisenberg and Dr. Lenfant, who speak to some of the issues before us today with their own very formidable experience and expertise, and I am really delighted to share this panel with them.

Over the last 30 years, we have developed a coverage process to assure access to medical advances for Medicare beneficiaries while protecting them from services of unproven effectiveness. Our goal is to continue to maintain and to improve a dynamic decisionmaking process, to produce consistent coverage guidance in the face of rapid changes in medical technology and health care delivery.

I am proud of the way in which our policymaking system is meeting that challenge. In recent years, we have undertaken a number of changes in the way in which we do things and we have approved a range of new technologies and interventions, such as ventricular assist devices, to provide a bridge for a transplant for beneficiaries in Medicare-certified heart transplant centers. More recently, we worked out with the FDA a process through which we can cover the majority of medical devices subject to investigational device exemptions, and we have begun to pay for portable ventricular assist devices to allow patients to leave the hospital while they await a transplant.

As I think you suggested, Mr. Chairman, every insurer and health care purchaser in the current environment has to deal with health policy and coverage policy. Private as well as public insurers, like Medicare, want to purchase high quality health care for the best price in an era of rapid changes in medical technology and extraordinary investments on the part of manufacturers.

In the case of Medicare, we have the particular requirements in the Social Security Act which provides that a technology or service must "be reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member." All of the Medicare coverage policy over the last 30 years has come from that basic statutory definition.

Interpreting this provision in the light of authoritative evidence gives us the ability to keep our benefits current. To assure we are living up to the standards in the statute as well as getting the best health care values for our beneficiaries, we apply to the assessment of new interventions or new technologies three criteria: a demonstrated effectiveness, appropriateness, and comparison with similar technologies.

By demonstrated effectiveness, we mean the extent to which authoritative evidence in the professional and medical community has established the benefits and appropriateness of a new technology. To make determinations as to demonstrated effectiveness, we rely heavily on technology assessment from agencies such as the Agency for Health Care Policy and Research, consensus conferences of the National Institutes of Health, the Veterans Administration, and the private sector medical community, particularly the specialty societies, as well. We, of course, have an extensive data base of our own which can inform this decisionmaking process and contribute to the work of these expert bodies.

In addition to determining whether or not a new procedure or technique is effective, we also have to be concerned with appropriateness, that is, the extent to which a service is suitable for but not in excess of the beneficiary's medical needs and conditions and is being provided by providers with the capabilities and skills to appropriately derive the benefit from the service.

Finally, we do compare new procedures or techniques with existing technologies. This does not mean we will decide whether or not to cover something on the basis of a cost-effectiveness analysis. We do not and will not make coverage decisions on the basis of cost effectiveness, and we will not refuse to cover services merely because they are costly. On the other hand, if a new service or technique is no more effective and less cost effective than the current technology in place, we believe we should pay no more for it than we do for the existing technology.

We make national coverage decisions after a thorough assessment of all the available data according to the criteria I have just described. In doing so, we frequently consult the Technology Advisory Committee, consisting of the medical directors from 10 of our carriers and representatives from the NIH and AHCPR, the Veterans Administration, the FDA, and CHAMPUS. Our national coverage decisions are binding on Medicare contractors.

When there is no national decision for a particular service, our contractors frequently issue local medical review policies describing

the circumstances under which an item or a service will be covered. In doing so, they are required to seek formal comment on such policies from the medical communities in their States and to give 30 days' notice before implementation.

We have a number of steps underway, outlined in my written statement, to improve coordination among the individual carriers and local medical policies and to use that increasingly as a basis to moving more quickly and efficiently to national coverage decisions.

All of us face the dilemma of often having to make decisions in the face of inadequate data. Many services come to be widely diffused without ever having been examined through controlled studies. We have a responsibility, we believe, as the Nation's largest payer, not only to make the right decisions consonant with the statute but also to help produce the data and the evaluations on medical effectiveness in order to improve the information base of our decisionmaking and that of others.

When reimbursement is provided before there is adequate clinical evidence to demonstrate the effectiveness of a new technology, that technology can diffuse rapidly, often inappropriately, in a way that significantly reduces our ability to ever adequately evaluate it. To address these kinds of concerns, we have begun to employ the device of what we are calling "coverage with conditions." We will use coverage with conditions only when existing data suggests a potential benefit to some patients but there is not enough data to predict the effect of generalized use of the technology or its long-term effects or appropriate patient selection criteria.

The conditions under which we will cover such procedures or services may include limitations on the use of the service or technology or may just require providers to collect data or to provide it under certain protocols.

Probably the most notable example of such coverage with conditions is our recent agreement with the National Heart, Lung, and Blood Institute regarding lung volume reduction surgery, a term that encompasses a set of procedures intended to improve lung function and relieve the debilitating symptoms for patients with chronic obstructive pulmonary disease. Despite very limited evidence of its efficacy, this surgery diffused very rapidly from 1993 to 1995.

In its 1997 appropriations conference report, Congress required us, with the advice and technical assistance of the Agency for Health Care Policy and Research, to report on the treatment of end-stage emphysema and COPD and on unilateral and bilateral lung volume reduction surgery. We were asked to review all available studies and make a recommendation as to the appropriateness and conditions of Medicare coverage for such procedures. We have provided a preliminary study of a preliminary version of this report as an appendix to my testimony and we present there the results of our review of 21 recently published articles on lung volume reduction study and on our findings from Medicare data bases.

Based on this review, we believe, number one, that the earlier AHCPR assessment, that the objective data do not permit a scientific conclusion about the risks and benefits of LVRS, is still valid; number two, that the implication that AHCPR, and we drew

from that study that this procedure should be covered only in the context of a controlled study, remains valid; and number three, that many of the weaknesses found in the data in the earlier formal technology assessment by AHCPR still exist. These weaknesses include study design problems, very brief followup periods, inconsistent measurement of important patient outcomes, and the failure to follow many patients after surgery.

This year, under our agreement with the National Heart, Lung, and Blood Institute, 18 clinical centers and 21 hospitals will begin to provide the service to Medicare patients and receive Medicare reimbursement. The study will include patients undergoing LVRS via two separate procedures, along with maximum medical therapy, and contrast them with patients receiving only maximum medical therapy. This study will allow us to identify and distinguish between the impacts of the surgery on patients' mortality, morbidity, quality of life, and on its impact on the disease itself.

I have tried to keep my prepared statement very brief. There is a much longer written statement, as you know. Obviously, we are happy to answer any questions, and I am sure my colleagues will add considerable insight to those very brief remarks.

Thank you again for the opportunity to be here, Mr. Chairman.

[The prepared statement and attachment follow:]

Statement of Hon. Bruce C. Vladeck, Administrator, Health Care Financing Administration

INTRODUCTION

Thank you for the opportunity to come here today and talk with you about how we make Medicare coverage policy. Over the past 30 years, we have developed a coverage process that assures access to medical advances for Medicare beneficiaries, while protecting them from services whose effectiveness is unproven. This is one of HCFA's greatest challenges in administering the Medicare program—to maintain a dynamic decision-making process that produces consistent coverage guidance in the face of rapid changes in medical technology and health care delivery.

I am proud of the ways in which our coverage policy-making system is meeting that challenge. For example, in recent years, we have approved ventricular assist devices to provide a bridge to a transplant for our beneficiaries in Medicare certified heart transplant centers. More recently, under our new program covering devices that are subject to an investigational device exemption (IDE), we have begun to pay for a portable version of this device that will allow patients to leave the hospital while they await their transplant.

In today's health care market, every insurer and health care purchaser must deal with coverage policy. Private as well as public insurers, like Medicare, want to purchase high quality health care for the best price. Health plans, whether public or private, managed care or traditional indemnity plans must control costs while still continuing to assure the highest quality of care for their subscribers. This cannot be done without authoritative evidence of the value of each individual service.

Medicare has emerged as a leader in the move toward such evidence-based decision making for coverage policy. We rely on state-of-the-art technology assessment and on agencies such as: The Agency for Health Care Policy and Research (AHCPR), The Food and Drug Administration (FDA), the National Institutes of Health (NIH), the Department of Veterans Affairs (DVA), the Department of Defense (DOD) as well as the advice of the medical community and private sector studies. Our own extensive reimbursement data contain additional useful information for assessing the effectiveness of all varieties of medical care. The experience from our program can benefit the entire health care marketplace.

Furthermore, the sheer numbers of beneficiaries that we serve and the wealth of information that we possess about them makes Medicare an important force in the market. We recognize that our coverage process also controls services provided by managed care plans that serve Medicare beneficiaries. Not only is the share of Medicare patients in managed care plans growing rapidly, but plans must provide these enrollees with the same Part A and Part B benefits that Medicare fee-for-serv-

ice beneficiaries enjoy. As a result, managed care plans have an increasing interest in our process being as scientific and thorough as possible.

Medicare coverage decisions probably also influence private plans' coverage decisions for their non-Medicare patients. However, many private plans now have sophisticated technology assessment and coverage processes of their own.

Many Medicare coverage decisions are made by our local carriers, based on the statutory requirement to cover only services that are reasonable and necessary for the diagnosis and treatment of illness or injury. In making their decisions, carriers depend upon the knowledge and advice of local physicians and other local specialists and on local medical review policies that are shared among carriers. HCFA has an overall interest in increasing the consistency of coverage policy among carriers and making national policy for coverage issues that are significant.

The Coverage Policy Process

Over the past 30 years, Medicare's coverage process has evolved from a relatively informal set of procedures for deciding on payment of particular claims, to a sophisticated process that includes extensive medical advice and state-of-the-art technology assessments.

The key to understanding Medicare coverage policy is its statutory foundation. The Social Security Act lists 55 categories of benefits that are covered under the program. They include physician services, inpatient hospital services, services in ambulatory surgical centers, and many more. The Act also gives the Secretary of the Department of Health and Human Services broad discretionary authority to go beyond these defined benefits to make coverage decisions on individual items and services. The law says:

"Notwithstanding any other provisions of this title, no payment may be made for items or services which ... are not reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member."

The interpretation of this provision, using authoritative evidence of whether a service is "reasonable and necessary," gives us the ability to keep Medicare benefits current in the face of changing medical practice.

The criteria used to make these decisions have evolved over time in response to our experience and to public comments and suggestions. The criteria that now guide the coverage process are: demonstrated effectiveness, appropriateness, and comparability to similar services. I will discuss each of these in turn.

Demonstrated Effectiveness

Demonstrated effectiveness is the first criterion for determining that a service or health care technology meets the Medicare coverage requirements. There must be authoritative evidence to establish that the benefits of a service or technology to the patient outweigh its reasonably anticipated risks. There must also be authoritative evidence to convince HCFA or its contractors that use of the service or technology will result in improved health outcomes (such as decreased morbidity or mortality or significantly increased quality of life, for beneficiaries or some groups of beneficiaries). In addition, items or services that are regulated by FDA must have received approval for marketing.

To find evidence that we consider authoritative in demonstrating the effectiveness of a service on patient outcomes, we examine:

- published articles based on controlled clinical trials, other controlled studies, and case series;
- formal technology assessments from recognized government and private entities, which examine both published and unpublished data;
- evaluations or studies initiated by Medicare contractors; and
- authoritative approvals of other agencies, such as FDA, that a service has therapeutic or diagnostic benefit for patients.

Sometimes these assessments are made by HCFA staff and our advisors. But with increasing frequency we are obtaining formal technology assessments from the AHCPR and other government and private organizations.

Assessments of health care technology have at least two features that are important to HCFA. First, rather than evaluating services in an investigational setting, they are focused on the effectiveness of technologies in general medical practice and on patient outcomes including morbidity, mortality, health status and health-related quality of life. Second, they use systematic methods for evaluating the quality of the scientific evidence available rather than relying on the less formal examination of medical opinion or consensus. They also grade the quality of the evidence based on

the study methods. We have adopted these evidence-based methods as our primary means for making Medicare coverage decisions.

The evidence-based environment increases the importance of giving the public access to HCFA while we are in the process of making coverage decisions. We have expanded the opportunities for interested parties to provide information and expert advice both before and after decisions are made. To ensure that our process for determining coverage is evidence-based, we consult extensively with interest groups and receive expert medical advice from both government and private clinicians. Our Internet Home Page is another means by which we hope to increase participation by interested parties. In addition, we are continually improving our communication methods with our contractors, who are often the first to become aware of the use of new health care technologies.

Appropriateness

Appropriateness means, to HCFA, that a service is suitable for, but not in excess of, the beneficiary's medical needs and condition. The qualifications of those providing the service and the setting where the service is provided may be a part of this criterion. The service must be furnished by personnel who are qualified by training, experience and licensure to provide that service and, in some instances, who meet HCFA-established training levels. The service must be furnished in a setting that is suitable for, but not in excess of, the beneficiary's medical needs and condition and must meet any facility requirements established by HCFA. For example, cardiac catheterization may be covered for some patients in a freestanding facility, but for patients with a high risk of complications, a hospital may be the only appropriate setting for receiving this service.

Comparison with Similar Technologies

It is apparent that cost-effectiveness analysis is extremely controversial for beneficiaries, providers and suppliers. It raises fears of rationing based on cost. HCFA has not and does not intend to make coverage decisions based solely on cost-effectiveness, and we will not refuse to cover services merely because they are costly. Moreover, manufacturers or providers do not need to submit formal cost-effectiveness analyses to HCFA in order to have a service considered for coverage.

Nevertheless, in order to become prudent purchasers of health care, third party payers, including HCFA, must consider the full value of any medical service they are considering for coverage. Cost-effectiveness analyses, when available, can be used in this regard. These analyses allow us to consider the full range of present and future costs and benefits of a service. Without it, payers and providers often focus on the present costs of expensive technologies rather than on the full value of the service.

Under specific and limited conditions, relative costs and effectiveness will be factors considered in determining Medicare payment policy. That is, if a service is more expensive but equally effective, it would still be covered and paid at the rate of the lower cost alternative. If, however, the service is found to be more effective for a specific group of patients, it could be paid at the higher rate. This criterion assures value for the Medicare program and its beneficiaries.

Local and National Coverage Decisions

The Medicare coverage process is sometimes confusing to the public because of the coexistence of national coverage decisions with those made locally by Medicare contractors. National coverage decisions are issued by HCFA after a thorough assessment of the statutory and clinical issues and analysis of the data. These decisions are binding on Medicare contractors. In the absence of national decisions for particular services, contractors have the discretion to issue local medical review policies.

Most Medicare coverage decisions are made locally, by HCFA contractors, according to the criteria that I just described and any applicable national coverage policy. Medicare contractors can issue local medical review policies to describe the circumstances under which an item or service will be covered. In developing such policies, our contractors are required to seek formal comment from the medical community who provide the item or service. Following the comment process, our contractors must publish final policies 30 days prior to implementation.

In addition, there are Carrier Medical Director (CMD) workgroups, national and regional meetings between the CMDs and HCFA, collaboration between carriers and the Peer Review Organization (PRO), and Carrier Advisory Committees (CACs), which represent medical physician specialties, beneficiaries and HMOs. All of these activities aid in the process of developing, revising, and gauging the impacts of the

development of local policy. All local medical review policies generated by a contractor are published; frequently the contractors conduct seminars, generate special bulletins, or use other methods to ensure that the medical community is aware of new policies. Though well planned and highly examined, such local policies have at times led to geographic variation in Medicare coverage that concerns our beneficiaries and providers.

HCFA cannot guarantee the consistency of Medicare coverage by directing local policy. However, local policies are shared among carriers and guide other carriers' local medical review policies. To increase the consistency of coverage, HCFA began a system of Carrier Medical Director workgroups to examine coverage issues. These groups pool resources and develop model policies, which operate to guide local policies. The model policy process is one way to increase consistency in coverage across the country for services that are not the subject of national policies. HCFA has also begun to issue a greater number of national coverage decisions to increase uniformity and to make our coverage policy more timely and flexible in response to available medical evidence. Issues are reviewed for national coverage for a number of reasons including high potential for the service to diffuse rapidly on a national basis; considerable local variation in coverage; or the availability of substantial amounts of medical evidence.

When we, at HCFA, decide to review a service for national coverage, we may perform an internal review of policy or consult with our technology advisory committee (TAC) consisting of ten carrier medical directors, including a managed care medical director, and representatives of NIH, AHCPR, VA, FDA and CHAMPUS. The TAC provides interchange between local and national policy and considers when an issue becomes of such prominence that it warrants a national policy. HCFA develops the agenda that the TAC will follow to evaluate and make its recommendations.

The TAC could recommend that HCFA: issue a national coverage policy, refer the issue for assessment by the Public Health Service or other qualified assessment organization, postpone the decision until there is more information, or decline to establish a new policy. HCFA can then accept or reject the TAC's recommendation.

Although TAC proceedings are closed to the public, the meeting agendas and minutes are now made available through HCFA's Home Page on the Internet. This is one of the means by which we hope to increase participation by interested parties.

Recent Innovations

All health plans, including Medicare, face the dilemma of having inadequate data to make evidence-based coverage decisions for some new technologies and services. Many services have not been adequately examined through controlled studies. Medicare payments for indirect medical education (IME) help contribute to the funding of health care research. As the nation's largest payer, Medicare recognizes its responsibility both to assist in producing data on the effectiveness of medical care and to provide access to valuable new technologies for Medicare beneficiaries as quickly as possible.

This responsibility is particularly vexing since the timing of technology assessments in relation to reimbursement for a service can be problematic. If assessments are done too early, the results from the investigation may not be generalizable to standard medical practice. Depending on such assessments would produce poor coverage decisions. But if reimbursement is delayed, due to lack of evidence, practitioners might cease using the technology before adequate data can be gathered.

The reverse situation is more common and creates even more of a dilemma. General reimbursement has often been provided before adequate clinical evidence exists. In such cases, a technology can diffuse rapidly, significantly reducing our ability to design the type of controlled study needed to provide good medical evidence.

To address these critical issues in coverage policy-making, Medicare has undertaken one of its most important efforts to date—"coverage with conditions." I will describe some of the recent steps we have taken.

Coverage with Conditions

Our recent decision to pay for certain lung volume reduction surgery procedures in conjunction with a clinical trial is an example of "coverage with conditions." This type of coverage may be used when existing data suggest a potential benefit to some patients, but there is not sufficient information to predict the effect of generalized use of the technology or its long term effects or appropriate patient selection criteria.

Coverage with conditions may include limitations of use, data collection, or the provision of the service under protocol conditions. These efforts may be implemented by making payments only to providers involved in a study sponsored by the Na-

tional Institutes of Health or other research organizations. The objective of coverage with conditions is to advance medical knowledge about the effectiveness of the services before they are diffused to general practice and to assure that Medicare beneficiaries are not put at undue risk from their use.

Only services that meet all of the following criteria will be considered for this coverage:

- the service is of substantial interest for Medicare coverage because it would potentially affect a large number of beneficiaries or provide an important new benefit to some;
- enough information exists about the service for HCFA to judge the service reasonable and necessary under particular conditions;
- the service is unproven with regard to questions remaining about risks and benefits that must be answered for a final coverage decision;
- the information necessary for HCFA to make a national coverage decision is unlikely to be developed by researchers unless coverage with conditions is offered; and
- any regulated services used with the service in question are approved for marketing by the Food and Drug Administration (FDA).

It is Medicare's long standing policy that, in general, services covered in clinical trials cannot be reimbursed because there is insufficient evidence of their benefits and risks. The above criteria differentiate coverage with conditions from clinical trials.

Lung Volume Reduction Surgery

An example of coverage with conditions is Medicare's recent agreement with the National Heart, Lung, and Blood Institute (NHLBI) regarding Lung Volume Reduction Surgery (LVRS). LVRS encompasses procedures intended to improve lung function and relieve the debilitating symptoms for emphysema patients. Despite the very limited evidence of its efficacy, this surgery diffused rapidly from 1993–1996.

In September 1995, a workshop on LVRS, sponsored by the National Heart, Lung, and Blood Institute (NHLBI) called for controlled studies of this surgery. A few months later, HCFA issued a policy of noncoverage for all LVRS based on the lack of medical evidence and the potential for morbidity and mortality among Medicare beneficiaries from LVRS. At the same time, we requested that the Agency for Health Care Policy and Research (AHCPR) perform an assessment of LVRS procedures.

AHCPR's assessment report in April 1996, said that the objective data did not permit a scientific conclusion about the risks and benefits of LVRS. AHCPR further recommended that the procedure only be covered within the context of a controlled clinical study. Later that month, HCFA and NHLBI agreed that NHLBI would design and fund such a study, now known as the National Emphysema Treatment Trial (NETT), and HCFA would pay for the medical care provided to Medicare beneficiaries participating in the study.

In its FY1997 Appropriations Conference Report, Congress required HCFA, with the advice and technical assistance of AHCPR, to report to Congress on the treatment of end-stage emphysema and chronic obstructive pulmonary disease and on unilateral and bilateral lung volume reduction surgery (LVRS). HCFA was asked to review all available studies and, based on this review, make a recommendation as to the appropriateness and conditions of Medicare coverage of such a procedures.

In the preliminary summary that accompanies this testimony, we present the results of our review of 22 recently published articles on LVRS and our findings from the Medicare databases. Based on this review, we believe that the conclusions of the AHCPR assessment are still valid, and their implications for Medicare policy the same. That is, LVRS should be covered only in the context of a controlled study. As described in the attached summary of our forthcoming report to Congress regarding LVRS, many of the weaknesses found in the data by AHCPR still exist. These weaknesses include study design problems, very brief follow-up periods and inconsistent measurement of important patient outcomes. Moreover, results may be biased as a result of many patients that were not followed after surgery.

Our analysis of Medicare claims data raised further concerns. We examined 711 Medicare claims for LVRS between October 1995 and January 1996. Of these patients, 26 percent had died by January 1997. Forty percent of the patients were hospitalized during the approximately 12 months following surgery. These patients averaged 2.1 acute care hospitalizations for a total of 20 hospital days. Sixteen percent of the patients had either a long term care hospital admission (averaging 30 days) or a rehabilitation hospital admission (averaging 24 days) The controlled study will allow us to identify and distinguish between LVRS' impact on these patients' mortality and morbidities requiring hospital stays and the impact of the disease itself.

This year, 18 clinical centers including 21 hospitals will begin to provide this service to Medicare patients and receive Medicare reimbursement. The study will include patients undergoing LVRS via median sternotomy or via video assisted thoracoscopy along with maximal medical therapy and patients receiving only maximal medical therapy in the non-surgical arm of the study. The study is scheduled to be completed in five years. The final study protocol is now being determined by the Executive Steering Committee for the study and will be completed by the end of May 1997.

Medicare payment for LVRS will be made only for patients who are participating in NHLBI's controlled clinical study of this new procedure. However, we are committed to modifying this policy quickly whenever new and scientifically conclusive data regarding the surgery confirm that it meets our criteria for coverage. For example, if the study's Data Safety Monitoring Board were to recommend and NHLBI to agree that some group of patients were achieving a clear benefit from LVRS, we would extend coverage to them at once. Likewise, a finding of clear ineffectiveness or harm for some patients would result in a noncoverage policy for that group.

Coverage of Category B Investigational Devices

Another type of coverage with conditions involves certain devices and drugs subject to FDA approval. It has long been our policy that items cannot be covered under Medicare until they receive approval for marketing from FDA. In September 1995, an agreement between Medicare and FDA regarding medical devices subject to investigational device exemptions (IDEs) led to a significant coverage policy change.

FDA agreed to classify devices with IDEs into two categories:

- Category A IDEs are experimental investigational devices, meaning that significant risk is being investigated.
- Category B IDEs are non-experimental investigational devices, meaning that incremental risk is being investigated, and that the fundamental issues of safety and effectiveness have already been resolved.

Those IDEs that were labeled "Category B," based on their substantial equivalence to existing devices, were made eligible for Medicare coverage while they are being studied for incremental risk. A condition of this coverage is that the service is being provided under the FDA protocol.

The President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry

We expect the recently created President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry to provide a forum for better understanding of the changes in the health care financing and delivery system and to provide valuable information to further inform our evidence-based coverage decision making. This high level commission, chaired by the Secretaries of Health and Human Services and Labor, includes representatives from the health care professions, other health care workers, institutional providers, insurers, purchasers, state government, consumers and experts in health care quality, financing and administration. Their recommendations for addressing the effects of the changes in health care financing and delivery will help public and private policy makers define appropriate consumer protection and quality standards.

Conclusion

The coverage process of the Medicare program has evolved over the years to meet the rapidly changing demands placed on it by the ever-increasing advances in medical science and technology. Like all health care insurers, it is our ongoing responsibility to define, clarify, review, and modernize the benefits under the Medicare program.

HCFA has been a leader in the trend in our health care industry toward evidence-based decisions and policies that provide needed scientific data to support medical effectiveness and outcomes. In today's environment, Medicare will continue to make coverage decisions and modify them whenever necessary to reflect new findings and data. It is vital that providers, suppliers, manufacturers and beneficiaries understand and participate in this process.

For more than 30 years, the Medicare coverage process has assured access to medical advances for beneficiaries while protecting them from unproven services, an accomplishment that continues to benefit the entire health care system. We plan to build on this success and to ensure that beneficiaries have access to those state-of-the-art technologies that preserve and support maximum well-being and quality of life.

Medicare Coverage of Lung Volume Reduction Surgery (LVRS)

Preliminary Report to Congress

In its FY1997 Appropriations Conference Report, Congress required HCFA, with the advice and technical assistance of AHCPR, to report to Congress on the treatment of end-stage emphysema and chronic obstructive pulmonary disease and on unilateral and bilateral lung volume reduction surgery (LVRS) and supplemental surgical methods. HCFA was asked to review all available studies and, based on this review, make a recommendation as to the appropriateness and conditions of Medicare coverage for such procedures. This preliminary report responds to that requirement. Additional information on the protocol will be forwarded at a later date.

Summary

Lung Volume Reduction Surgery encompasses procedures intended to improve lung function for emphysema patients and relieve debilitating symptoms of the disease. LVRS diffused rapidly from 1993–1996, despite a paucity of medical evidence concerning its safety and efficacy. Moreover, there are considerable debates within the medical community not only about the appropriateness of surgical intervention, but also concerning the relative merits of a variety of surgical approaches, appropriate selection of patients, and the contribution of comprehensive pulmonary rehabilitation.

In December 1995, HCFA issued a noncoverage policy for all LVRS procedures based on the lack of medical evidence and potential for extensive morbidity and mortality among Medicare beneficiaries. HCFA also requested that the Center for Health Care Technology (CHCT) of the Agency for Health Care Policy and Research (AHCPR) undertake a complete review of available evidence, published or unpublished. Over the same period of time, the National Heart, Lung and Blood Institute (NHLBI) also became interested in the medical issues concerning LVRS. A September 1995 workshop sponsored by NHLBI called for controlled studies. In April, 1996, the CHCT report was released. Based on an analysis of approximately 2800 patients from 27 institutions, the report concluded that the available data did not permit a scientific conclusion regarding the risks and benefits of LVRS. The report recommended that since some patients appeared to benefit in the short run, Medicare coverage might be provided within a controlled clinical study. Later that month, HCFA and NHLBI signed an agreement to participate in such a study. As part of this agreement, NHLBI would design and fund the study and HCFA would provide reimbursement for the medical care services provided to Medicare's beneficiaries in the study.

The clinical study, for which protocol has not been finalized, may include as many as 9000 patients. The study represents a precedent setting cooperative effort between the nation's largest payer and its premier science agency for research on pulmonary diseases and may serve as a model for future assessments of important new technologies. Medicare beneficiaries will be provided controlled access to a promising but in many ways unproven procedure, while scientifically valid data to guide future use and reimbursement decisions are generated.

As is true for many new technologies in the U.S. health care system, many parties are interested its rapid diffusion. Emphysema affects millions of individuals with substantial disability, morbidity and mortality. LVRS offers hope of improved quality of life for some of these patients. Because of the potentially large number of patients that might be eligible for this surgery, there is also a considerable financial interest in LVRS on the part of providers and manufacturers. Therefore, it is understandable that there would be questions about the cautious approach to LVRS represented by the clinical study. This report will provide comprehensive answers to such questions. It provides detailed explanations of the study, an assessment of recent data concerning LVRS and details of how modifications to Medicare coverage policy will be made.

What Do Recent Published Data Suggest About the Appropriate Course of Action for Medicare?

We reviewed 21 recently published articles regarding LVRS for this report. A set of evidence-based criteria for systematic review was applied, including examination of study design, outcomes measured and patient follow-up. In addition, we examined

Medicare databases in order to provide supplemental information on patients' morbidity and mortality following surgery.

The conclusion from this review is essentially the same as that of the AHCPR/CHCT assessment and an assessment for the American Lung Association. While some patients appear to benefit for a short period of time in terms of selected measures of lung function and exercise capacity, the most critical questions concerning the risks and benefits of LVRS for particular patients cannot be adequately answered by existing data. Indeed, the data review heightened the importance of producing scientifically valid evidence concerning the durability of any benefits and mortality during a reasonable post-surgical period. Thus, the most appropriate course for Medicare on behalf of its beneficiaries remains the cautious and scientific path reflected in the NHLBI/HCFA clinical study. That is, the data suggest enough potential for benefit that some Medicare coverage should be provided, but only under the conditions present in a clinical study that will generate the medical evidence needed to answer critical questions about the value of this surgery.

These conclusions result from several inherent weaknesses in the published data concerning LVRS. First, the published articles present case series data rather than evidence from clinical studies. While the authors involved should be commended for reporting outcomes data, case series are generally considered as a weak and potentially misleading form of evidence concerning the effect of therapeutic interventions. Moreover, while an important test for the value of LVRS will be its risks and benefits over a reasonable time period—e.g. 1–2 years—most available studies report patient experience at 3 months. In addition, the majority of studies measure what are considered surrogates for the patient outcomes of interest. Thus, the impact of LVRS on quality of life, use of medical care services and mortality is yet to be determined.

In addition to the problem of these data being available for a relatively short time after surgery, an important issue regarding these studies is that a substantial number of patients are lost to follow-up. This problem is particularly true for data beyond the 3 months post-surgery and may result in considerable bias for reported outcomes. The most comprehensive study examined outcomes at 6 and 12 months. Two-thirds of the patients could be followed for 6 months and one-half for 12 months. Of those that could have been followed at 12 months, 26% were missing. The study reported favorable changes in some outcome measures at 12 months. To the extent that such numbers of missing patients differ systematically from those that can be followed , any reported change in outcomes may be due to such selection bias rather than any effect of the surgery.

Finally, analysis of Medicare claims raises related concerns. Beginning in October 1995, a specific ICD–9 code was assigned to LVRS. We identified 711 claims for LVRS that used this code between October 1995 and January 1996. Of these patients, 26% (185) had died by January 1997. Moreover, 40% are hospitalized post-surgery, averaging 2.1 admissions and 30 hospital days in the 12 months following the surgery. Sixteen percent of the patients had either a long term care hospital admission (averaging 30 days) or a rehabilitation hospital admission (averaging 24 days). The fact that LVRS patients are a high risk for both morbidities requiring hospital stays and mortality during the post-surgical period requires careful examination. In particular, the controlled study will allow us to distinguish between LVRS's impact on these measures, and the impact of the disease itself.

The NHLBI/HCFA Clinical Study

The study is a multi-center clinical trial designed to determine the efficacy of two surgical approaches to bilateral lung volume reduction, median sternotomy and video assisted thoracoscopy. Efficacy will be determined with regard to a variety of patient outcomes including lung function measures, exercise tolerance, medical care service use, a variety of quality of life measures and mortality. Eighteen study centers, including 21 hospitals has been chosen for the study. The study is scheduled to be completed in 5 years.

Patients will be randomized to either of two surgical groups with maximal medical therapy, or a group that will receive only maximal medical therapy. Maximal medical therapy includes state of the art medical care and intensive pulmonary rehabilitation. The randomized design is chosen for two reasons. First, current data do not allow for a conclusion regarding the relative risks and benefits of LVRS or the contribution to outcomes of maximal medical therapy. Therefore, there should be no pre-disposal as to the preferred course of treatment. Second, because there is no existing data on the natural history for this group of patients, many of the most critical questions about the risks and benefits of LVRS can only be answered within a randomized design.

The final study protocol is being determined by the Executive Steering Committee comprising the principal investigators and investigators from the study's coordination center is expected to be completed by the end of May. Patient enrollment will likely begin this summer. The study also includes a Data Safety monitoring Board (DSMB) which regularly reviews the study data. If at any time the DSMB finds that data conclusive—that is, one of the study treatments is providing clear benefit or harm—they will recommend either the study be terminated or the protocol be modified.

FUTURE MEDICARE COVERAGE DECISION AND THE CLINICAL STUDY

Soon Medicare reimbursement for LVRS is provided only within the context of the clinical study. However, HCFA is committed to modifying this policy rapidly in response to new and scientifically conclusive data regarding LVRS. The explicit contingencies for modification of Medicare coverage are part of the agreement between HCFA and NHLBI.

First, current coverage is conditioned on the study protocol and changes automatically in response to study design and analysis of evidence. The initial protocol required approximately 1300 patients each in surgery and maximal medical therapy. These patients are expected to be enrolled within 18 to 24 months of the implementation of the study. Unless the data demonstrate harmful effects, Medicare coverage will be continued in a manner consistent with the evidence. More importantly, Medicare will respond immediately to any finding of conclusive evidence by the DSMB and NHLBI. For example, if the DSMB were to recommend and NHLBI agree that some group of patient were achieving a clear benefit from LVRS, coverage would be expanded. Depending on the evidence, such expansions might take place in the study centers, or new criteria established for its provision in hospitals outside of the study. Likewise, a finding of clear ineffectiveness or harm for some patients would trigger a noncoverage policy targeted to that group.

Conclusion

We believe that the scientific, yet flexible approach to coverage of LVRS outlined in this report remains the appropriate policy course for Medicare. HCFA strives to assure access to safe and effective services for Medicare beneficiaries, while not providing reimbursement for ineffective and harmful services. Despite a number of published articles regarding LVRS, a scientific conclusion concerning the relative risks and benefits of these procedures cannot be made from existing data. By providing coverage within the clinical study, Medicare is making a precedent setting effort to provide controlled assess to a promising, yet unproven procedure while assuring that the needed medical evidence is created.

Chairman THOMAS. Thank you, Mr. Vladeck.
Dr. Eisenberg.

STATEMENT OF JOHN M. EISENBERG, M.D., ADMINISTRATOR, AGENCY FOR HEALTH CARE POLICY AND RESEARCH

Dr. EISENBERG. Thank you, Mr. Chairman. Good afternoon, Mr. Chairman, and Members of the Subcommittee. It is a pleasure to join you today in my first full week as the new Administrator of the Agency for Health Care Policy and Research, AHCPR. I enjoyed my work for you as Chairman of the Physician Payment Review Commission, and I look forward to continuing to work with you in the years to come.

I know that this Subcommittee knows well that there are gaps in our knowledge about medical effectiveness and that these gaps lead to wide variations in coverage and wide variations in the use of health care services. For example, the rate of prostate biopsy in Dallas is 30 per 1,000 Medicare beneficiaries, whereas in McAllen, Texas, the rate is 8 per 1,000, less than one-third the rate in Dallas. Which is better? We need to know.

Mr. Chairman, I want to make two points at the outset about technology assessment. The first one is that when we refer to technology, we are not only referring to expensive or high-tech services like lung volume reduction surgery. We are also referring to the vast array of what is called little-ticket technologies, like pap smears, lab tests. The use of these technologies can add up to big expenses, but in the long run, some of them can also save money.

For example, an AHCPR-funded research project indicated that the use of low-tech strategies to prevent pressure ulcers could, in just two States, New Hampshire and Vermont, save Medicare more than $1 million annually.

A second point is that as the variation in prostate biopsies suggests, there is a need for more scientific information that is related to the appropriate use of technology and that that does not end just with the decision about coverage. Even when coverage is not an issue, clinicians and patients need the latest scientific information to determine whether a procedure is appropriate, for which patients, and when in the course of their disease.

The evaluation of lung volume reduction surgery is a good example of how we can respond to this need for evidence about what works in medical care. Unless we address the need for this type of scientific evidence on the benefits and on the costs of medical technology, I am concerned that we run the risk that future efforts to contain health care spending will not be informed about the effectiveness of these new services and could, in fact, inhibit innovation.

Let me comment briefly on the role of the Agency for Health Care Policy and Research in providing the scientific information that is used in making informed decisions, not only about coverage but also about the best way to use covered services.

First, this agency conducts and supports research on the effectiveness and the cost effectiveness of services, like prostate disease.

Second, we conduct and we support research on involving patients in these treatment choices. For example, an AHCPR research project developed something called a "shared decisionmaking program" which includes a video disk for use by patients who have prostatic enlargement. It helps them to make informed choices among the options that are available to them, and pilot studies have shown that these patients, in fact, choose surgery less often.

Third, we conduct and we support research on medical information technologies, like CHESS, which is the Comprehensive Health Enhancement Support System. This is a system developed by researchers at the University of Wisconsin that enables patients to make decisions about the services that they need and to understand their diseases better. This has resulted in these patients having lower health care costs and fewer and shorter hospitalizations.

Fourth, we conduct and we support research to improve the methodology to assess technology. For example, AHCPR supports the development of outcomes and effectiveness measures, like an index for a visual function impairment in patients who have cataracts.

And fifth, this summer, we will fund about 10 evidence-based practice centers around the country that will provide public and private organizations with scientific information that will help

them to improve the quality, effectiveness, and the appropriateness of clinical practice.

Mr. Chairman, from my personal research before entering government last week and from AHCPR's experience in technology assessment, I think we face a number of important challenges. Let me mention three.

First, both the public and private sectors need to devote more resources to technology assessment, which, in the long run, can enhance the quality of medical care and give us more value for our limited dollars.

Second, the results of this technology assessment must be in the public domain so that all potential users of this technology or this service can be informed, especially patients and those small health plans who do not have the resources or the ability to do the research themselves.

And third, we need collaboration, collaboration between plans, the scientific community, and the developers of these innovative technologies to collect data on patient outcomes and costs and to use the best scientific methods available, particularly randomized control trials.

Mr. Chairman, I believe that increased collaboration between the public and the private sectors is critical to ensure that we increase innovation while at the same time maintain high quality and value in our health care system. I think we can build the evidence and the science base to provide both the public and the private sectors with timely and accurate science-based information to help patients and clinicians make informed coverage and utilization decisions.

Thank you.

[The prepared statement follows:]

Statement of John M. Eisenberg, M.D., MBA, Administrator, Agency for Health Care Policy and Research

INTRODUCTION

Good Afternoon Mr. Chairman and members of the Subcommittee. It is a pleasure to appear before the Subcommittee in my first full week as the new Administrator of the Agency for Health Care Policy and Research (AHCPR). I enjoyed my work for you as Chair of the Physician Payment Review Commission, and I look forward to working with you in the years to come. I especially want to thank you for giving me the opportunity today to address the issue of evaluation science and how it relates to coverage decisions in our health care system.

Market forces have spawned unprecedented changes in our health care system. The health care market today is characterized by intense price competition, with purchasers demanding greater accountability and value. These pressures are leading health plans and facilities to give increasing scrutiny to capital investments and decisions to cover new medical procedures or services. In an atmosphere of constrained resources, it is hardly surprising that we are facing increasing demands to prove that we are getting real value for the health care dollars we spend. Unfortunately, decision makers often lack the scientific evidence on effectiveness that would help them judge the relative value of alternative health technologies.

One result of our shortage of scientific evidence is our health care system's wide variation in use of services. Often, this occurs when there is ambiguity on the effectiveness of the procedure or service. There is also variation in what services are covered. For example, a recent study on laser therapy demonstrated that there is substantial variation in coverage on new technologies. A 1994 General Accounting Office Report found substantial variability among Medicare carriers with respect to denial rates for services screened for medical necessity (GAO Report, 1994).

Variation also exists in medical practice among states and local jurisdictions. For example, the rate of prostate biopsy in Dallas, Texas is 29.6 per thousand of Medicare enrollees, compared to McAllen, Texas where it is 8.3 per thousand of Medicare

enrollees (Wennberg, 1996). Health services research has shown that these differences can be attributed in large part to a lack of knowledge regarding the efficacy and effectiveness of medical technologies. (Steiner, 1996 & 1997). A study examining the high variability in the use of electroconvulsive therapy found that a primary cause was the lack of knowledge regarding the effectiveness of the procedure (Hermann RC, 1995).

Another consequence of inadequate evidence on effectiveness is that old technologies linger even when they have been surpassed by better ones. In 1989, I published a study that examined old and new technologies in hospitals and found that new technologies did not replace older technologies, but were simply added to the hospital regimen. For example, we found only a small reduction in one older technology, oral cholecystogram, after the introduction of a new and clearly better technology, gallbladder ultrasound (Eisenberg, 1989).

The lack of scientific evidence on the effectiveness of medical procedures and technologies is troublesome: it complicates the treatment decisions physicians and patients face, makes it difficult for plans to make appropriate coverage decisions, and can lead to appeals of coverage decisions in court.

Technology and the Cost of Medical Care

Mr. Chairman, let me make two points at the outset. First, when I refer to technology, I am not only referring to expensive high-technology devices such as magnetic resonance imaging, but also to the vast array of "little ticket" technologies, such as pap smears and other common medical procedures and services. These small-cost technologies can add up to big expenses. For example, an AHCPR funded recommendation for preventing pressure ulcers led to the finding that use of low-tech treatments for pressure ulcers could, in just two states, New Hampshire and Vermont, result in Medicare savings of over $1 million annually.

Second, as my earlier prostate example suggests, the need for scientific information related to the appropriate use of technology does not end with a medical coverage decision. Even when medical coverage is not an issue, clinicians and patients need the latest scientific information to determine whether the procedure or service is appropriate in each specific instance. They need to balance carefully the risks and benefits of every medical intervention and any alternatives for each individual patient's circumstances.

This is critically important because there is a growing body of scientific research that demonstrates that patients often receive services that are not clinically indicated. For example, researchers at the RAND Corporation found that up to 30% of patients whose medical records they reviewed received medical procedures that were not appropriate when measured against rigorous clinical standards established by experts. They also concluded that the appropriateness of another 10% of procedures was equivocal (RAND Studies). Other researchers have estimated that only 20% of technologies now used in the practice of medicine have been specifically evaluated (OTA Report, 1994).

When medical technology is used appropriately, it can improve health, and in some instances, reduce costs. For example, in 1991, AHCPR conducted a technology assessment on laparoscopic cholecystectomy on behalf of Health Care Financing Administration (HCFA). Based on AHCPR's recommendations, HCFA covered this procedure, which has subsequently resulted in reduced hospital length of stays. This finding is borne out in a recent study funded by AHCPR, in which patients with laparoscopic cholecystectomies had hospital stays that were one-third less than those who underwent the standard surgical procedure.

Another example is AHCPR's assessment of routine laboratory tests in end stage renal disease (ESRD) for patients undergoing dialysis. In 1994, there were 200,000 individuals receiving dialysis at a cost of $7 billion annually. An AHCPR health technology review found that there was little scientific data to support the routine use of some of the tests performed in patients undergoing dialysis. Clearly, millions of dollars can be attributed to the cost of testing—some of which is unnecessary.

At the same time, technology can increase costs. Excessive and inappropriate use of new drugs, devices, and other services is driven by many causes—economic incentives for physicians and hospitals, the practice of defensive medicine, and insurance systems that pay for technological interventions more generously. Poor understanding concerning the effectiveness and outcomes of medical technology is also a contributing factor.

Another problem is the use of ineffective technology, which can raise costs but not improve patient outcomes. Also, the rapid rate of development and diffusion of new and promising technologies often means that timely data are not available to make a scientific judgment regarding their effectiveness. A recent study found that a ma-

jority of medical directors of health plans cited the lack of timely data on the safety, effectiveness, and cost-effectiveness as the major barrier to establishing optimal coverage decisions. As a result, we need to develop innovative approaches to acquire the necessary data (Steiner, 1996).

AHCPR's technology assessment on lung volume reduction surgery (LVRS) is a case in point. This technology assessment concluded that there was insufficient evidence on which to make a scientific judgment regarding the effectiveness of LVRS. AHCPR recommended that coverage be granted within the scope of a clinical trial, which is now being conducted by the National Institutes of Health. AHCPR is supporting the cost-effectiveness component of that trial. It is significant that this study will also include measures of patient preferences and of quality of life, because the role of these factors are an important component of the scientific knowledge we hope to derive. It is our hope that the collaborative efforts between the NIH and AHCPR will yield the information needed to make an informed coverage decision on LVRS.

Another mechanism that should be explored as a complement to clinical trials to evaluate technologies is the "Centers of Excellence" approach that was used in coverage of cardiac transplants. These Centers are defined by having a demonstrated expertise in performing a given procedure or technology. Additionally, patients are registered and outcomes and effectiveness data are collected throughout the episode of care to help further refine the technology or procedure being performed.

Working Together

Approaches involving cooperation between an insurer (in this case, Medicare), the scientific community, and advocates of new technology will become increasingly essential in the years ahead. Unless we address the need for solid, scientific evidence on the benefits and costs of medical technology, we run the risk that future efforts to contain health care spending will inhibit innovation. This could mean that better technology—even more cost-effective technology—will not be developed, and American leadership of a global industry could be lost.

The role of the government is pivotal in this regard. It is the largest purchaser and provider of health care services, accounting for at least 45% of all health care spending. For some procedures federal dollars account for the lion's share of expenditures. For example, Medicare and Medicaid expenses for coronary artery bypass graft procedures exceed $8.7 billion and represent 56% of the total expenditures for this procedure (AHCPR, 1992). As a purchaser of medical care, the federal government has a compelling interest in technology assessment and those decisions need to be based on the best scientific information available.

Through the work of the National Institutes of Health and AHCPR, the federal government also helps to build the underlying research, the basic science for technological innovation and its assessment. In addition to conducting technology assessments for HCFA and the Department of Defense, AHCPR supports work that is critical to the field of technology assessment, such as:

- the effectiveness and cost-effectiveness of alternative treatments and services provided in community settings (including stroke and cardiovascular disease, prostate disease, diabetes, and pneumonia and other common conditions);
- research on the functional outcomes of treatments for patients and the importance of involving patients in treatment choice. For example, an AHCPR research project developed a "Shared Decision Making Program," which included an interactive videodisc for use in helping patients with benign prostatic hyperplasia make informed choices among treatment options. Pilot studies have shown that patients who view the vidoeodisc choose surgery less often than other patients;
- the development of medical information technologies such as computerized patient records, computerized decision support systems, hospital and ambulatory care data systems that provide the ability to conduct this research while providing additional resources to clinicians. For example, an AHCPR-supported study found that AIDS patients who use the Comprehensive Health Enhancement Support System (CHESS) had fewer visits to doctors office, or spent 17% less time in doctors' offices. These patients have lower health care costs and fewer and shorter hospitalizations. AIDS patients using CHESS had 20% lower treatment costs overall; and
- research to improve the methodology underlying technology assessment. For example, AHCPR supports the development of outcomes and effectiveness measures such as the "VF–14," an index of functional impairment in patients with cataracts.

Our research demonstrates that technology assessments, done scientifically[1] can provide the infrastructure to help reduce practice variation and to allow for informed decision making. This summer we will implement our new Evidence-Based Practice Center program through which we will provide public and private sector organizations with scientific information to improve the quality, effectiveness, and appropriateness of clinical practice. The Centers' evidence reports will provide critical evaluations of the available scientific literature regarding clinical interventions and technologies. The topics for the evidence reports will be selected from nominations by the private and public sectors. With the support of the Appropriations Committees, we have set aside funds for this effort and will fund about 10 evidence based practice centers this summer. The Centers will better enable AHCPR to serve as a "science partner" for both the public and private sector. These reports will also assist HCFA, DoD, VA, states, and private sector purchasers to make informed decisions on the effectiveness or appropriateness of specific health care technologies.

Next Steps

Mr. Chairman, from my work in the area of technology assessment and the experience of AHCPR in technology assessment, I conclude that we face a number of important challenges in this area:

- Both the public and private sector need to devote more resources to technology assessment. Choices are being made everyday in the health care system. These choices run the risk of being determined solely by cost considerations, unless we assure that the scientific evidence is available to make informed decisions. Failure to address this will put medical innovation at risk. It is interesting to note that, as a proportion of national health care expenditures, total funding for technology assessment in other nations is 18 to 160 times higher than in the U.S. For example, technology assessment expenditures in France are 22 times higher, (Holohan, Lancet 1996) despite the fact that its population is 2 times greater than the Medicare population alone.
- The results of technology assessments need to be in the public domain so that all potential users of the technology or service can be informed. The important methodological details of publicly funded research are by definition available to all those interested in how results were reached. Interested parties may include patients/consumers, providers, plans, and providers. The same access may not be granted for research done for proprietary reasons. Additionally, small firms such as biotechnology start-ups, may not have the resources to conduct effective outcomes studies alongside their basic science and clinical investigations.
- We need creative collaborations between plans, the scientific community, and developers of innovative technology to collect data on patient outcomes and costs. Without better approaches to securing these data in timely manner, we will never be able to assure that medical coverage decisions are based on science rather than economics. We can't ignore patients in this mix. One of their concerns is that cost may limit their access to the latest medical technology. The President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry, on which I serve as deputy chair, is likely to address this issue as it develops a patient's bill of rights.
- We have a responsibility to provide the latest scientific information on technologies to clinicians and patients as well as to those making coverage decisions. This information is critical to the appropriate use of technology in day-to-day practice. There already is a lot of health related information in the public domain through the Internet and popular media. Unfortunately, much of it is conflicting and anecdotal. Patients need unbiased science-based information to help them make better health care decisions in consultation with their doctors.

Mr. Chairman, I believe that increased collaboration between the public and private sector is critical to ensure that we increase innovation, while at the same time maintain high quality and value in our health care system. By doing this, we can build the evidence and science base to provide the public and private sector with timely, accurate, science-based information to make informed coverage decisions.

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[1] Technology Assessment Criteria: Use of an explicit and defined process; Careful selection and definition of the topic; Public participation; Comprehensive search for the highest quality evidence available; Review and rating of the evidence; Use of analytic techniques appropriate to the level of evidence found; Review of the draft assessment both by experts and potential users; Update of the assessment when appropriate; Evaluation of the process and its results.

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Chairman THOMAS. Thank you very much, Doctor.

Dr. Lenfant.

STATEMENT OF CLAUDE LENFANT, M.D., DIRECTOR, NATIONAL HEART, LUNG, AND BLOOD INSTITUTE, DEPARTMENT OF HEALTH AND HUMAN SERVICES, NATIONAL INSTITUTES OF HEALTH

Dr. LENFANT. Thank you very much, Mr. Chairman.

I am pleased to have the opportunity needed to address the Subcommittee and to share our views on lung volume reduction surgery, or LVRS. This, as you well know, is a much debated issue among the medical community.

The Institute became involved in early 1995 when members of that community approached us with their concerns about the increasing use of this procedure despite the fact that its effectiveness had not been demonstrated. This led to a consensus workshop that recommended a randomized study to rigorously assess, first, the effectiveness of the procedure, and then which patients would benefit from it.

Through its own process, HCFA reached a similar conclusion. It approached us, and we agreed to join forces to conduct the study which is now ongoing.

With this background, I would like to make four points about clinical trials in general and this one in particular. First, we believe the LVRS trial to be not only appropriate, but necessary, to give both patients and their physicians the information they need to make informed, intelligent decisions about treatment of end-stage emphysema. History, Mr. Chairman, is full of promising treatments, medical and surgical, that when evaluated under controlled conditions, failed to live up to expectations of benefits and, in some cases, caused harm.

Second, we consider a randomized clinical trial the only way to answer the question of whether LVRS helps or harms patients. Simply comparing patients before and after treatment ignores the possibility that factors other than the operation may have come into play.

Third, as with all clinical trials considered by the National Institutes of Health, the data will be continuously scrutinized by an independent scientific board called a Data Safety and Monitoring Board, or DSMB. I should underscore that the board will be independent from the investigators and independent from the agency.

As part of its review of the protocol before the trial begins, the DSMB will examine all available data on LVRS to ensure that the protocol is valid in terms of what is known today. If the board concludes that an identifiable subset of patients clearly benefits from LVRS, the DSMB can and will recommend that the criteria for entry into the trial be modified accordingly.

The DSMB can also recommend changes in the protocol, even after it is underway, if data show that a certain group of patients is highly likely to benefit from the surgery. The DSMB has the power to recommend early termination of the trial if the data show a clear benefit or risk from the intervention. In this regard, you may have seen a couple of days ago an announcement in the Washington Post on the termination of a clinical trial regarding a procedure for heart disease, which was more effective than the other procedures.

Fourth and last, Mr. Chairman, I would like to underscore that a trial is the fastest, most efficient, and most accurate way to provide the information we need. Without it, billions of health care dollars may be spent, tens of thousands of patients may be exposed to the risk of an unproven treatment, and the value of LVRS will forever remain in doubt.

So to conclude, Mr. Chairman, in our views, this is not an issue of rationing or limiting access to a procedure. This is to establish that patients are not exposed to an unnecessary risk.

Thank you very much. I will be pleased to answer your questions.

[The prepared statement follows:]

Statement of Claude Lenfant, M.D., Director, National Heart, Lung, and Blood Institute, Department of Health and Human Services, National Institutes of Health

I am pleased to have this opportunity to address some questions that have arisen regarding lung volume reduction surgery (LVRS) and the Lung Volume Reduction Clinical Trial supported by the National Heart, Lung, and Blood Institute (NHLBI) and the Health Care Financing Administration (HCFA). Today, I would like to tell you exactly why the NHLBI got involved with the LVRS issue; why a randomized trial is the only valid way to determine the benefits and risks of LVRS to patients; why such information is critical to patient decision-making; and why the approach adopted by the NHLBI is the fastest, most efficient, and most accurate way to provide that information.

WHY IS THE NHLBI INVOLVED?

In early 1995, members of the medical community discussed with the NHLBI widespread concerns that hundreds of patients were receiving LVRS despite the fact that its effectiveness had never been established. The only results we had were preliminary, nothing was known about the long-term outcome, and no scientific evidence was available to indicate which patients might benefit from the operation.

In response to these concerns, the NHLBI convened a workshop in September 1995 to elicit the views of experts in pulmonary medicine, thoracic surgery, physiology, outcomes assessment, quality-of-life evaluations, and statistics on LVRS. They concluded that although LVRS was a promising procedure, it "must be evaluated in a scientific, coordinated, and cooperative fashion." They recommended that the NHLBI "develop a mechanism for funding data collection and analysis from a multicenter study" and that "a randomized study with a controlled nonsurgical arm ideally should be undertaken to evaluate the procedure critically." Thus, by the time HCFA approached us, the NHLBI was already firmly convinced that a critical evaluation of LVRS was scientifically indicated and essential.

The preponderance of professional opinion supported the NHLBI in this view. Moreover, the American Thoracic Society, the medical section of the American Lung Association, adopted a position paper on LVRS in May 1996, stating "the conduct of clinical trials, preferably in a controlled, randomized fashion, is urgently needed."

Why a Randomized Trial?

A randomized clinical trial is the only way to answer the question of whether LVRS helps or harms patients. In the absence of such a trial, we have no idea whether this operation represents an improvement over current treatments and whether it has unacceptable risks. To date, LVRS has been performed on a very select group of patients (only 10 to 30 percent of patients referred for the procedure are considered suitable for the surgery), and we do not know how they would have fared without surgery. Simply comparing patients before and after treatment ignores the possibility that factors other than the operation may have come into play. Only a randomly selected control group allows evaluation of the true effect of the treatment.

Our experience has demonstrated the importance of a control group time and time again. It was impressively illustrated in the NHLBI Cardiac Arrhythmia Suppression Trial (CAST). That study was designed to assess the effects of antiarrhythmic drugs, since heart arrhythmias are associated with a several-fold increase in death rate after heart attack. Although the drugs did, indeed, suppress the arrhythmias, they were also associated with higher death rates compared to placebo. Results were so dramatic that the trial was terminated early. The surprising increase in mortality would not have been apparent if the investigators had not included a control group that had received a placebo.

Experts on clinical trials overwhelmingly agree that control groups are the best way to avoid incomplete or misleading conclusions. A control group allows for reliable detection of subtle or subjective, but nevertheless important, treatment effects such as quality of life. If the effect of the treatment is large, then a control group allows us to detect it even faster and with more certainty. Thus, constructing a rigorous trial design with a control group ultimately serves patients better.

It has been argued that having a nonsurgical control group is unethical because it denies some patients access to LVRS. However, one must bear in mind that LVRS is a treatment of unproven efficacy. On the other hand, the medical therapy that is included in the trial design is the best established therapy currently available for severe emphysema, and all patients in the trial will receive it.

Why Do Patients Need This Information?

History is full of promising treatments, medical and surgical, that when evaluated under controlled conditions failed to live up to expectations of benefit and, in some cases, caused harm. Can we ever forget thalidomide? And in the area of surgery, consider the recent example of extracranial-intracranial bypass. Based on comparison of clinical outcomes among nonrandomized cohorts of patients, this operation was believed to prevent strokes; however, to the surprise of many, a large multicenter randomized trial revealed that it did not prevent stroke, but only exposed patients to the discomfort and risks of major surgery.

We consider the LVRS trial to be not only appropriate, but necessary to give both patients and their physicians the information they need to make informed, intelligent decisions about treatment of end stage emphysema. How can physicians competently and ethically advise their patients about LVRS when they have no sound scientific basis for doing so?

Although determining efficacy and setting guidelines for which patients are likely to benefit from LVRS will not guarantee a good outcome for all patients, it will increase the chances of success for most patients and, at the very least, allow patients to make decisions based on widely accepted scientific data, which do not now exist. Patients have the right to know objectively whether the chances of success outweigh the risks.

WHY THE NHLBI APPROACH?

The NHLBI approach is flexible; it encourages continuing input from the best scientific minds in the community and relies on the investigators themselves to develop the full protocol and the manual of procedures that will guide every detail.

As with all NIH clinical trials, the data from the program will be scrutinized at least quarterly by an independent scientific board called a Data Safety and Monitoring Board (DSMB) whose responsibility it is to review the protocol for its scientific validity, oversee the performance of the centers and investigators, assess the quality of the data, and evaluate the intervention's risks and benefits to the participants. As part of its review of the protocol before the trial begins, the DSMB will examine all available data on LVRS to ensure that the protocol is valid in terms of what is known. If the board concludes that an identifiable subset of patients clearly benefits from LVRS, the DSMB can recommend that the criteria for entry into the trial be modified accordingly. The DSMB can also recommend changes in the protocol, even after it is under way, if data show that a certain group of patients is highly likely to benefit from the surgery. The DSMB has the power to recommend early termination of the trial if the data show a clear benefit or risk from the intervention, as was the case in CAST. We require this periodic review by an independent, scientific peer group in all of our clinical trials to ensure their safety, fairness, and scientific validity.

Because of the unusual demand to have this procedure evaluated quickly, I have charged the investigators to have a protocol ready by June 1997, just one year after the release of the request for proposals. This is a rapid timetable, indeed, but I have every reason to believe it will be met.

CONCLUSION

End-stage emphysema is a devastating chronic illness, and its victims are desperate. LVRS is a palliative treatment that has emerged without adequate scientific validation of its efficacy. This trial represents our best opportunity to provide it. If we fail to conduct the trial, we will be failing in our mission to serve the American people. Billions of health care dollars may be spent, tens of thousands of patients may be exposed to the risks of an unproven treatment, and the value of LVRS will forever remain in doubt.

I will be pleased to answer any questions the Committee may have.

Chairman THOMAS. Thank you, Doctor.

Bruce, when I am looking back at the 1989 proposed regulations, trying to put myself back in that timeframe, where those proposed regulations stated, "if a service were to be viewed as marginal with respect to safety and effectiveness but expensive in comparison with available covered alternatives, we think the cost-effectiveness considerations are appropriate."

I think almost anyone with very little effort can come up with a dramatic example which clearly indicates the value of a procedure. I think the doctor did it in his testimony in terms of the control group with the placebo. It is dramatic.

The one that I use for example a lot of time was the one that was publicized, oh, maybe more than 1 year ago now, maybe 2 years, the open heart surgery versus angioplasty, where one is obviously more invasive but the end result is the same, and so why in the world would you go through the greater risk to the patient to get the same result.

We have those kinds of examples. They are very dramatic and they do a great job in a 20-minute speech. But when you start dealing with the entire list of services and procedures, you begin to get into a situation where the marginality of the tradeoff does not—it is a clear area in which people could debate forever.

What I am trying to do is get back into that 1989 mind, if you would help me, because we are currently facing a discussion with the Congressional Budget Office on the cost effectiveness of a number of preventive procedures, and they persist in indicating to us that there is a cost associated with these, and we are trying to explain to them, No, it saves money.

Well, the difference between their position and our position is time and that something that may be more expensive or require a payment at the front end over time is, in fact, cost effective, if you look at the total dollars that would have been spent. What was the mindset in the late eighties, the early nineties, or even now in terms of a timeframe reference vis-a-vis what you would call cost effective? I understand it between two procedures like open heart surgery and an angioplasty, but there are so many others that you do not get that clear and dramatic difference. What is the time factor in cost effectiveness, if any?

Mr. VLADECK. Mr. Chairman, let me separate my answer into three parts, if I could. The first is to say that I will not pretend to speak for the folks who wrote the proposed regulation in 1989, but I think they were trying to address a particular problem which we do encounter all the time as new technologies appear in health care. That is the question of what to do with the availability of a new technology or a new procedure, a new device, frequently, that is very, very much more expensive than the one it replaces and where the incremental benefit associated with the new device is very small.

Chairman THOMAS. Well, I have a question with that, as well, in terms of the cost versus effective benefit.

Mr. VLADECK. I think the issue there is, frankly, that we have come to the position that even if it is no more effective than the preexisting technology, it should be made available in terms of Medicare coverage, but it is not at all clear that we should pay the incremental costs unless there is an incremental benefit, and that is the way we are now thinking about these issues.

Second, the issue of——

Chairman THOMAS. On that point, though, just let me say that is a dilemma that would have been, in my opinion, a far greater one in 1989 in the old virtual cost-plus world. Today, with the fixed-price system, and this is a question I want to give to Dr. Eisenberg, I do not think we have fully seen a blossoming of technology in a fixed-price world because, to me, technology is a tool and it is directed where it is most appropriately believed to be used, and in a cost-plus world, it was a more expensive, marginal benefit on the physical or mental aspect.

But in a fixed-price world, you are going to see technology turned in a different way and that is what concerned me so much about taking a 1989 mindset and assuming cost effectiveness in today's world. So I have another question along that line, but keep going. You have two more points.

Mr. VLADECK. Thank you. And I quite agree that the issue of cost effectiveness is different in a world of fixed prices, capitation, or fee schedules than it was in earlier times.

And second, I would say, relative to the scoring of preventive benefits, for example, in the Medicare Program, if you look at the

economic literature on cost-effectiveness analysis or cost-benefit analysis, which I used to teach, one of the things that is central to such analyses is the discount rate, the issue of time. If you invest $1 now and get $1.50 back 50 years from now, that is not a good investment.

But that is one of the reasons why we have moved away from a more classic or traditional notion of cost benefit into thinking about the Medicare Program and Medicare coverage, because the benefits are incommensurate if they have to do with increased function, with better health or greater longevity for beneficiaries. Then they are just incommensurate with any dollar outcome and you cannot compare 6 years of added life expectancy per 1,000 people with any number of dollars. It is just not an appropriate thing to do. So we do not try to look at coverage issues in that kind of old-fashioned cost-benefit terms at all.

Chairman THOMAS. No, but I do think you could take a look at someone who did not receive the ability to detect and did not receive the appropriate education to manage a disease like diabetes and take a look at what we are paying out on end-stage renal disease that would not have been paid out.

Mr. VLADECK. Again, I think those arguments are very complicated and very tricky, but frankly, I do not think those are the grounds on which we or the Congress, to be honest, should make Medicare policy. If we know a way that can improve the health of Medicare beneficiaries and that has demonstrated effectiveness, and where it is very clear, such as earlier intervention with borderline diabetics, we should provide coverage. For example, if it is going to reduce the long-term morbidity for diabetics, we ought to do it and we should not get caught up in some of the very arcane theoretical cost-effectiveness arguments at all.

Chairman THOMAS. And how do we determine if that is the case?

Mr. VLADECK. Again, I think we have a set of mechanisms through the process of technology assessment, through authoritative organizations like some of the specialty societies, like the National Institutes of Health and so forth. We have a fair amount of consensus on some issues of well-established practice in the medical community.

Chairman THOMAS. Do you believe the Government and those agencies you just mentioned have as good of cost-effectiveness analysis tools as those people who are in the business of providing the services under managed care structures?

Mr. VLADECK. Mr. Chairman, I am trying to distinguish two issues. One is effectiveness and the second is cost effectiveness, and I am saying I think the Government experts on effectiveness from a clinical point of view are, in many ways, in fact, the gold standards on effectiveness. People all over the world look at NIH consensus statements or other formulations of opinion as a standard of practice.

Cost effectiveness is a different issue, and that is why, as I say, we do not think it is appropriate, except when comparing two technologies that produce the same outcomes, for Medicare to look at cost effectiveness as the basis for a coverage decision.

Chairman THOMAS. You indicate that Medicare is the Nation's largest payer, and you indicated that we really do need some out-

comes research. Well, I would suggest to you that, more and more, we are paying, the taxpayers are paying for private entities to collect some very valuable data which they are using to improve margins in their structure which apparently are pretty cost effective and, to a degree, they are able to make decisions which could possibly be a quantitative and qualitative mix decision, which allows them to do as much as they can in a very cost-effective manner, if we use the term that way. And they are doing it because we are paying for it.

What is it that HCFA needs, if anything, to be able to get that information from those people who are collecting it? Apparently, it is fairly valuable because from a proprietary point of view, they are not out peddling it to other folks. What is it that HCFA is doing or can do or needs from Congress to do to set up a structure for the statistical information which would allow us a terrific data base for outcomes research?

Mr. VLADECK. We have——

Chairman THOMAS. With full privacy protections, I have to add that, for the individuals, physicians, and all others.

Mr. VLADECK [continuing]. We have had a number of conversations, Mr. Chairman, with both the American Association of Health Plans and a number of their component plans about working jointly on technology assessment in a variety of ways, and we have talked in those instances about sharing data.

But I think it is fair to say that they feel themselves to be operating under some of the same constraints and limitations that we are. That is to say, to actually observe clinical practice through claims data or outcomes data, the kind of information that most of the plans themselves have available, is not going to produce, as quickly as more controlled studies might, the quality of information that permits you to make a determination about the real effectiveness of a new procedure or new technology.

So many of the plans are beginning to talk about joining us in the sponsorship of particular controlled studies in one sort or another or letting us share some of that activity, because they understand that they have to make decisions all the time in order to operate, just as we do. All of us are working in a world with less good information than we would like.

Chairman THOMAS. There is no question about that. Obviously, as you look in a prospective sense, it makes all kinds of sense to do these kinds of studies. But I just have got to believe that there are a number of payments that are being made in different ways between different regions which, if you collected that data, you could examine a cost-effective approach to it and end up getting more for the taxpayers' dollar than you currently get.

Are you telling me that the cost of setting up computerized patient records and beginning to collect this kind of data in a standardized way costs more than the data is worth?

Mr. VLADECK. I am saying, Mr. Chairman, that for purposes of evaluating the effectiveness of a new procedure or a new technology or even for comparing the effectiveness of, say, a surgical approach to benign prostate disease with a medical approach to benign medical disease, that the number of aspects of the patients' conditions and circumstances that are relevant to doing good

science argues for the limitations of using what is essentially a claims-based or encounter-based system for doing decisions of that effectiveness, that you need some control of a trial in order to get, in a relatively timely way, relatively conclusive answers.

But again, I think both of my colleagues are much more expert in the science of this than I am, and if I may, I would defer further answer to them.

Chairman THOMAS. Fine. One question, though, because, obviously, we are moving more and more, at least in terms of enrollment figures, into a managed care world, and if you want to make any comments about what may work in terms of a cost-effective analysis in a fee-for-service world versus Federal versus local carrier policies and assessing in the same manner an integrated or managed care structure. Is that causing us more problems, or do you have a way out?

Mr. VLADECK. No, Mr. Chairman. I think the cliche or the stereotype is that whereas in the fee-for-service sector, we have very powerful economic incentives to overprovide new technologies or new services, then in the managed care sector, there may be an incentive to underprovide those.

I think our conversations——

Chairman THOMAS. Well, let me ask a more directed question if you are going to direct it in that area because what we have seen is a series of consolidations which are, in essence, producing a national structure, and you are still making decisions on a regional basis. Do you agree with that?

Mr. VLADECK. Well, I would——

Chairman THOMAS. Do you have complete consistency between regions or locale?

Mr. VLADECK. No. We are still making decisions on a local basis.

Chairman THOMAS. What does a managed care structure that pushes for uniformity and integration do with a national structure which allows for local inconsistencies? Are they required to follow local inconsistencies or do you create a standard for them that they utilize, not withstanding others having to follow local inconsistencies? What do you do?

Mr. VLADECK. My impression is, Mr. Chairman, based on conversations with executives at the two largest, or two of the three largest managed care companies that are seeking to build national programs, that they are not much further along than we are in bringing some degree of national uniformity to the practice patterns of their locally based plans.

Again, I think we have to push——

Chairman THOMAS. Having said that, what do you do?

Mr. VLADECK [continuing]. For national——

Chairman THOMAS. Do you require those national plans to follow the local inconsistencies?

Mr. VLADECK. What we require them to do is when we have a national policy, to follow the national policy. When we have inconsistent local policies—the issue has not arisen—we cannot expect them to follow inconsistent policies. They will have to follow one or the other. But we have very few instances in which the local policies are inconsistent. What is much more common is that we have many in which we have local policies in some communities and no

explicit coverage policies in the rest of the country. We can fix the inconsistencies relatively quickly. It is how quickly we can move to national policies that remains more of a problem.

Chairman THOMAS. Let me ask the question of you and you can throw it to either of your colleagues, if it is more appropriate that they answer it. But as you know, Congress is dealing with a number of issues, one of them doctor-patient relationships in a number of areas. How do we deal with, without a fairly solid data base by which we can produce fairly good factual outcome research and guideline arguments for a physician, how do we deal with what could be a very clear conflict between the payer, the procedures the payer wishes to follow, the doctor-patient relationship, and what the physician believes is an appropriate procedure?

Mr. VLADECK. Let me make a quick observation about that and see how my colleagues want to react. In the Medicare fee-for-service program, we have long taken the position that a licensed health professional can provide any service that the patient wishes which he may legally or she may legally provide in the State in which they are practicing, but that that does not require us to pay for any such procedure, that what we pay for has to be consistent with the law and the criteria of necessity and appropriateness.

I think most private insurers behave the same way. Once you get to a managed care arrangement or a capitated arrangement, I think there is a real question as to the potential for a conflict or a disagreement between an individual physician and the protocols, guidelines, or rules that a particular plan may seek to apply.

In that regard, we have taken essentially two positions. One is that there must be total freedom of expression on the part of the physician to tell the patient what his professional judgment is about the best treatment for a particular illness. Second, that we need to substantially improve the rules under which patients or physicians who are unhappy about a plan's policy in a particular instance can ask for a reconsideration. We need to significantly clarify the Medicare rules around that issue very soon.

Chairman THOMAS. Let me give you a real world example and tell me how you would work it out. Both the National Cancer Institute and HCFA issued regulations on the mastectomy question in which, ultimately, the decision to hospitalize, to do it inpatient or outpatient, was the decision of the physician and the patient. The President, on the other hand, held a press conference and indicated that he was supportive of legislation which would mandate a fixed hospital stay for that procedure.

Why would HCFA come down for a position which would allow the physician and the patient to make the decision, and do you believe that would be a cost-effective approach vis-a-vis locking in a specific number of days legislatively for any particular medical procedure?

Mr. VLADECK. We are very comfortable with the position we have taken, and, I believe, had there been a specific piece of legislation that extended exactly the same policy to all private plans, the President would have been very comfortable in endorsing it, although I can never speak for him in that regard. There was no such legislation and, therefore, we have supported the legislation that came closest to achieving the same objective.

Chairman THOMAS. Thank you very much.

I do want you to come back when we talk about the Tax Code, where you make the point that $1 invested now and you only get $1.50 in 50 years is not a good investment. We will be considering a capital gains tax in terms of reward for risk taken over time and I anticipate your indicating that that is a very good idea. Thank you. [Laughter.]

Mr. STARK. I have a whole bunch of questions, Mr. Chairman, but I guess they deal with coverage somewhat. Let me try just in the area of appeals. Let us suppose, particularly under managed care, Bruce, if a beneficiary for an HMO is not satisfied with the primary care doctor's recommendation, they can appeal, right?

Mr. VLADECK. That is correct.

Mr. STARK. But the HMO is not required to accept the appeal, is that correct?

Mr. VLADECK. They are required to either consider it or to say that they are not going to reconsider it so that the patient can take it to the next level of the process.

Mr. STARK. All right. What can the beneficiary do if the HMO will not accept the appeal? What is the next step?

Mr. VLADECK. In general, there are——

Mr. STARK. No, specifically. Where do you go?

Mr. VLADECK. If it is an issue of whether or not the HMO will pay for a certain service, the beneficiary can ask an independent contractor to reevaluate the HMO's determination.

Mr. STARK. You mean the independent contractor being the paying agent?

Mr. VLADECK. Being, I am sorry?

Mr. STARK. The intermediary?

Mr. VLADECK. No. We actually have a separate contractor to handle the HMO appeals.

Mr. STARK. What if the HMO just will not grant the procedure?

Mr. VLADECK. What if the HMO will not grant the procedure?

Mr. STARK. Yes. You want to have a heart transplant and the HMO says no. Then what do you do in a timely enough fashion so you do not die while you wait for an answer?

Mr. VLADECK. There is a problem in that under our existing rules, while there is a process both within the HMO and outside it, it can be too long for a patient with an emergency situation. We have made it clear that as soon as we can complete all the paperwork, we are going to amend our rules to address those situations and to provide for much more rapid turnaround of the process in urgent or emergent situations.

Mr. STARK. You are about to issue some new regulations, right?

Mr. VLADECK. Yes, sir.

Mr. STARK. Will the patient be able to appeal without getting permission from their primary care doctor to appeal?

Mr. VLADECK. Yes, absolutely.

Mr. STARK. That is changed from your draft rule, so they can go right——

Mr. VLADECK. I think there has been some misunderstanding of the role of the physician in that regard. The appeal is a patient decision.

Mr. STARK. And the doctor does not have to give them permission to appeal?

Mr. VLADECK. That is correct.

Mr. STARK. But that doctor can deny the appeal?

Mr. VLADECK. No. If the patient is appealing a decision by a primary care physician, it is not that physician himself making the determination. Now, there does need to be some mechanism that we believe requires a physician has an opportunity to weigh in on the question of whether or not the appeal is an emergency or not. But whether or not the appeal is undertaken, that is up to the beneficiary.

Mr. STARK. And you have some time limits in your new rule?

Mr. VLADECK. Yes. We will be proposing new time limits.

Mr. STARK. Like 48 hours?

Mr. VLADECK. I think in the range of 48 to 72 hours.

Mr. STARK. That is good. Thank you.

Now, I have another problem, and I think I understand your problem, but I have been trying to get you to replace an antinausea drug which is covered when you give somebody an IV, but they now have an oral form that costs half as much and you say, correctly, we do not pay a pharmaceutical benefit, which I guess the pill would be but an IV is not. I suppose you could get aspirin as an IV, right? So if, in fact, you would say, Well, we will pay for a pill in lieu of an IV, you have just created a pharmaceutical benefit, which is not such a bad idea, by the way.

But is there any way in some high cost areas to save a lot of money, where previous to the introduction of a pill form it was only available intravenously and, therefore, we could capture some of these savings on some of these pharmaceutical breakthroughs, or do you need a law changed?

Mr. VLADECK. Mr. Stark, I have spent more time on this issue and——

Mr. STARK. OK.

Mr. VLADECK. Let me just tell you, as I understand it, I think it was OBRA 1993 which provided for the coverage of outpatient cancer chemotherapeutic agents and the question has been—and covered them for a pill form if we would previously have paid for them in the intravenous form. The issue is whether the antinausea drugs meet the statutory definition of anticancer drugs and we have tried to draw this line about 87 different times. Frankly, this requires a legislative fix, which we would be more than happy to have.

We understand the principle. We agree with the principle. We just cannot get a consistent interpretation from our counsel that makes sense of the existing statutory language, and we would be more than happy to work with the Members in both parties of both houses to get this fixed as soon as there is an appropriate vehicle to do so.

Mr. STARK. Madam Chairman, one final question. We have some criticism today on HCFA's timeliness in coverage decisions, but the question is also being raised about how managed care plans decide on coverage. Should not a managed care plan, including the PSOs, have, at a minimum, the coverage that reflects Medicare's policies? Is there any reason that we should not stipulate that a managed

care plan must cover all of Medicare's benefits, and would you have a way to enforce this if we did not?

Mr. VLADECK. We have an absolute requirement that is already in the statute that, at a minimum, a managed care plan that enrolls Medicare beneficiaries must provide those beneficiaries the same benefits as they would get in the fee-for-service Medicare system, and we have interpreted that always to mean the results of the most recent and up-to-date coverage policies.

Now, we have one exception to that policy which we made several years ago, I think for logical reasons, but it may require some reevaluation. When we make a coverage policy decision in the middle of a year, such as the coverage of transplants which might have a major effect on the cost to the plans under a rate that has already been established for the year, they have until the start of the new rate year to change their rates. But other than that, our coverage policies are binding on the plans as they are adopted.

Mr. STARK. The question comes is that if you cover heart transplants—you do, right?

Mr. VLADECK. Right.

Mr. STARK. Do you?

Mr. VLADECK. Medicare does.

Mr. STARK. OK. But my managed care plan primary care doctor says, "I will not do it." Where are we?

Mr. VLADECK. If you are a Medicare beneficiary——

Mr. STARK. He has to do it?

Mr. VLADECK. No. You have to appeal and seek a reconsideration of that decision. And again, once we get our new rules out, if you are in an emergency or urgent situation, you are entitled to a reconsideration within 72 hours.

Mr. STARK. Absent that, should not a licensed physician's second opinion be almost prima facie? Let us go back to a hip replacement, if that is a thing you do, and Kaiser says they will not do it for me and I go down the street to a surgeon who does that and he says, "You should have it." If I were in Medicare, I could have it, right? If I were not in a risk contract, I could get it?

Mr. VLADECK. Right.

Mr. STARK. Should I not, therefore, be able to get it without having to go through an appeals process? Should I not just be able to go find a licensed professional who says, "If you need it, I will——"

Mr. VLADECK. A Medicare beneficiary in that situation has two choices. Choice number one is if the doctor in the HMO says no surgery, and there is a doctor across the street, not in the HMO, who says you need the surgery, the Medicare HMO patient can appeal both within the HMO and then through an external review the HMO's decision, or the Medicare beneficiary may disenroll and return to their previous Medicare coverage.

Mr. STARK. But, I might suggest, that is just what an HMO-network doctor would like. In other words, what a great thing to avoid costly procedures. Then as a doctor, you know I am going to get it, so you say, "I am not going to do it," disenroll, go across the street, charge Medicare a fee-for-service which they cannot get under the capitated plan, and——

Mr. VLADECK. And that is why we have to, as part of our monitoring of HMOs, look very carefully and increasingly carefully, more carefully than we have in the past, at patterns of disenrollment and utilization by recent disenrollees.

Mr. STARK. Thank you, Madam Chairman.

Mrs. JOHNSON [presiding]. Thank you.

Mr. Christensen.

Mr. CHRISTENSEN. No questions.

Mrs. JOHNSON. Mr. McCrery.

Mr. MCCRERY. Mr. Vladeck, let us focus for just 1 minute on your decision not to cover lung volume reduction surgery. Can you expand a little bit on how HCFA arrived at that decision? How did the issue arise in the first place? Were you getting questions from intermediaries about whether it was covered? Was it related to increased utilization of the procedure? Would you go through that for us?

Mr. VLADECK. Yes, sir. In the fall of 1995, two things happened roughly at the same time. One, we began seeing a very rapid increase in claims for this procedure, particularly in some parts of the country, not everywhere in the country, but in some communities in particular.

Second, there was at the same time, as Dr. Lenfant discussed, the convening of a meeting, I believe at the request of the professional societies in the first instance, at the National Institutes of Health in which representatives of the American Thoracic Society and some of the other professional groups, both medical and surgical, involved in the management of chronic pulmonary disease expressed concerns about the diffusion of this procedure in the absence of better evidence about it.

As a result of that information and everything else we could find in the literature at that point, we made a decision effective January 1, 1996, to discontinue coverage of the procedure. Sometime before we announced that decision, we also asked the Agency for Health Care Policy and Research to do a technology assessment for us on the quickest turnaround basis that they could, and I believe that was provided to us in March or April 1996.

That further reinforced our belief that, to the extent we covered this procedure, it should be done only in the context of a very carefully controlled trial, and it was at that point that we worked out with NHLBI the plans to conduct such a trial.

Mr. MCCRERY. Thank you. Do you have a regular procedure for reviewing services that are covered, and do you regularly remove services or products from coverage?

Mr. VLADECK. Our system is very much biased and asymmetrical in that regard, in part because years ago, our General Counsel advised us as to that position. They maintained that we have the discretion under the statute to make a determination about whether or not to cover something new as a relatively routine administrative process, but to discontinue coverage of something we have covered in the past requires a formal rulemaking procedure, which is, of course, a much more complex and onerous process.

So we formally discontinue coverage of certain things periodically, but we do much less of that and probably much less than we should. If once or twice a year we publish a proposed discontinu-

ation of coverage, that would probably be the average or above average, whereas we are making decisions to cover new things on a continuous basis.

Mr. MCCRERY. When you do go through this relatively unusual procedure of removing something from coverage, what is that usually based on? What considerations are involved in that?

Mr. VLADECK. It is generally based on reports from our carrier medical directors and from the medical community that some procedure is now considered to be obsolete or ineffective, or no longer an adequate or satisfactory approach to treatment of a certain illness or problem, so that it is something the medical profession has left behind and that only those practitioners who have not yet gotten the news might still be doing. So that is another reason why it is a relatively infrequent event for us.

Mr. MCCRERY. What about considerations like the general utility of the procedure or the medical device, for example, excess utilization, perhaps? Are those things considered——

Mr. VLADECK. Certainly in my tenure, which is the only thing I can speak of without having to do more research, I cannot think of an instance in which we have sought to withdraw coverage of something we were already covering for any reason other than growing professional consensus that it was not a desirable or useful thing to do.

Mr. MCCRERY. Thank you.

Mrs. JOHNSON. Mr. Christensen.

Mr. CHRISTENSEN. Bruce, while we have got you, I want to ask you a question on the AAPCC and what the administration is looking at this year as far as working with us on this issue. Last year in our bill we got it up to roughly $350. What are your thoughts and what is the administration looking at this year in terms of the overall Medicare?

Mr. VLADECK. I think there are four pieces—let me see if I can get them all in the right order—to the managed care payment proposals in the President's budget.

The first is to adopt the $350 floor. No county would get a rate lower than that.

Second, to adopt something similar to the blend that was talked about in which over a 4-year period, we would phase in from 100 percent locally based rates to a rate structure that was 30 percent national rates and 70 percent local rates, which would shrink all of the differences nationally.

Third, we have proposed to pull out of the AAPCC the dollars attributable to graduate medical education, both direct and indirect, and disproportionate share hospitals, and to pay those directly to the hospitals that would have received them, had the patients been in the fee-for-service sector.

And fourth, in addition, we have proposed an adjustment of one time in the year 2000 to account for the overall selection bias in the program and to reduce the level of payment, on average, from 95 percent of the AAPCC to 90 percent of the AAPCC.

And then on top of all that, we have put in a series of "hold-harmless" provisions so that in any given county from one year to the next, except in the year 2000, the rates will not actually go down. That is to say, if you pull out all the teaching and dispropor-

tionate share or if you have a very high rate county moving to the national average, we have tried to cushion the year-to-year disruption of putting all these changes into place at the same time.

If you look at where this gets you as compared to the very different sort of procedures or processes that were contained in the Balanced Budget Act or some of the other legislation that was talked about in the last couple of years, I do not think the end point is that different. Certainly, the goals of reducing the geographic variation of raising the floor dramatically in rural counties and of making sure the teaching and DSH money gets directly to those institutions are very similar to those in the previous legislative proposals. I think the way in which we get to them may be a little different, but I think after 5 or 6 years, they come out in a reasonably similar place.

Mr. CHRISTENSEN. Do you really think, though, that the fourth point, of overall selection, is going to help bring equity to the geographical imbalance? You know the map and you have seen what the maps look like as far as all the areas that are 10 or 20 or 30 percent below, say, what Dade County is and what some of the other areas are. Do you really believe the fourth point that you mentioned of overall selection can help bring equity to this area?

Mr. VLADECK. Again, the floor is still the floor, so if you have a county that is now getting $230 a month, for example, as the AAPCC, their floor is $350 a month, even after we have reduced the national average.

So the fact of the matter is, the lowest cost Medicare counties in the United States, as I am sure you know, are in Western Nebraska, and we are paying at the moment something like $235 or $240 a month in the fee-for-service sector for Medicare beneficiaries in those communities. We think from a payment point of view, that $350 floor is more than enough of a response to the payment problem.

There are other problems getting managed care and particularly Medicare managed care into rural counties. We think our proposals to contract directly with provider-sponsored networks will address some of those problems. The proposal that would permit us to pay provider-sponsored networks on a partial risk basis, if they elect that, may help some of them get into the business.

Also, we are phasing out the so-called 50–50 rule for counties where you will never get enough commercial enrollment to sustain that, and that package of activities taken together should radically alter the prospects for the development of Medicare managed care programs in rural counties throughout the country.

Mr. CHRISTENSEN. Bruce, I really hope that that is the case because there are a lot of us on the Hill that are fairly upset about the equity involved here, and bringing up the floor to $350 is not going to solve the inequitable nature of a Dade County, Florida, provider contractor receiving twice what an Omaha, Nebraska, provider contractor receives. I look forward to working with you on this and hope we can get something resolved.

Mr. VLADECK. I think this ought to be an area in which we can come together reasonably quickly. I think there is a lot of commonality of feelings about this.

Mr. CHRISTENSEN. Thank you.

Mr. VLADECK. Thank you.

Chairman THOMAS [presiding]. Does the gentlewoman from Connecticut wish to inquire?

Mrs. JOHNSON. Yes. I want to ask three rather narrow questions, because I know many of us want to hear all the people on the next panel and the day is full of things.

First of all, it is my understanding that Medicare does not cover people in clinical trials. That is correct, is it not?

Mr. VLADECK. As a general policy, we have not. That is correct.

Mrs. JOHNSON. As a general policy. I am concerned about that policy. First of all, it means our clinical trial information is not senior-sensitive, and we went through this with NIH. We found out that their biggest heart study had not included any women, and we knew a lot about heart disease in men but we did not know much about heart disease in women. We have gone through this with AIDS, assuming that what we were seeing in male patients was true for female patients, too.

I think it is very important, actually, for Medicare to cover seniors in clinical trials so that as we do these clinical trials, we do see the process of some of these diseases in older Americans, as well, and have some better ability to estimate, frankly, the cost when something comes out of a clinical trial, ready to be a covered item.

So I think we are doing ourselves a big disservice as well as seniors a big disservice by having a policy that does not cover seniors in clinical trials.

Mr. VLADECK. I agree with you, Mrs. Johnson. Throughout the history of the Medicare Program, as we have read the statute, we have refused to pay for experimental treatments or therapies. However, recognizing some of the concerns you have expressed, we have been in discussions with the National Institutes of Health for the last year or so to try to establish some ground rules or some procedures under which we could participate in selected clinical trials.

Frankly, it has run into the following snag, which we will get by, but it is illustrative of some of the problems we have. Something like 80 percent of the clinical trials underway at any given time at the National Cancer Institute, which has far and away the most extensive program of clinical trials in the NIH, involved the tests of new cancer drugs which would be administered ordinarily on an outpatient basis, and thus, in most instances, are not covered by Medicare.

But we have talked with Dr. Lenfant. We have talked with folks at other NIH institutes about building on the lung volume reduction model to more systematically and more routinely participate in clinical trials when there is an intervention with potentially important implications for the Medicare population. We expect to be doing a lot more of that in the future.

Mrs. JOHNSON. I would really like to work with you on this——

Mr. VLADECK. OK.

Mrs. JOHNSON [continuing]. Because I think just because something is an oral treatment does not mean that it may not work differently in elderly people than it does in other ages. I think we need the information that clinical trials develop in order to, in a

sense, provide the public guidance on drug usage that clinical trials are supposed to provide us with.

So I would see our participating in that as something we would do as a matter of public interest and national policymaking than as a separate decision as to whether after the clinical trial is complete, we are going to cover that drug.

So if there is a legal impediment to this, I would like to know it, because I have had legislation in this area for a couple of years, but it is drawn rather broadly, frankly. But I would like to make sure we address this because our experience in the past with narrowly based science in health care has not been good.

That leads me into my other issue that Mr. Stark raised earlier, and that is we are also finding oral cancer drugs that do not have any IV equivalent. They are better than that. But it does seem to me that we need to focus on this issue and address it legislatively, if necessary, of cancer treatments that are either the equivalent of or better than the IV treatment, and if they are less costly, at least as a temporary stopgap measure, I think we need to address that.

I understand the complexity of its relationship to the fact that Medicare does not cover prescription drugs, but if not having the prescription means that you have to go to the hospital and get the IV treatment and pay the extra money and also the extra inconvenience and possibly not have as good an effect, I think we have to be able to deal with that, so I am interested in trying to work with you——

Mr. VLADECK. We would be happy to try to work with you on appropriate language.

Mrs. JOHNSON [continuing]. But if you could give us some proposed language and meet with us, there are at least two of us here who are really interested.

Then last, let me just point out to you a bill that Connie Morella has put in for a number of years and I am a cosponsor of having to do with bone density screening. Now, we pay for bone density testing, but we wrote the regulations, I think it was in 1974, and so there is enormous variation across the country in access for seniors to bone density treatment, and it is not necessary. We know a lot about this now. We know a lot about the difference between being on a hormone therapy and not on hormone therapy. There is a pretty good body of knowledge that is established as to when bone density treatment is beyond a shadow of a doubt necessary.

I think it is important that you move ahead to rewrite those regulations and get it out there. If you need legislation to push you, I will do that, but otherwise, we are already paying, so this is probably not going to be a cost item, but we do not have equal access. We do not have a science-based approach.

Mr. VLADECK. We understand that. We expect within the next few months to receive both a technology assessment from the Agency for Health Care Policy and Research and some proposed coverage guidelines from the National Osteoporosis Foundation, and as soon as we have those two documents available and have a chance to read and analyze them, it is our intention to revise the coverage policy for bone density exams.

Mrs. JOHNSON. I would urge you to get together the cosponsors of that legislation so that we can see if there is any way that you

need us, but equally important, if there is any way that we can help to disseminate your actions.

Thank you.

Mr. VLADECK. We should have more information on that for you this summer.

Mrs. JOHNSON. Thank you very much.

Chairman THOMAS. Thank you, folks. Any additional questions for the panel?

The only thing that I am concerned about, and this is a problem that is easy to voice in the larger sense, and I am looking for some indication from anybody if they believe a study could deal with the quality of life factor. Everybody talks about the cost of medical intervention in a timely way in a lifespan structure, and if we cannot get into the measurement of quality versus quantity, how do you make a decision on a cost-effective basis? If you do it between procedures and totally disregard the age and the ability of the patient to receive any time benefit from the procedure, it is fairly troubling to me.

Dr. Eisenberg, was there any indication that perhaps a quality of life factor could be built into an analysis of a cost-effective study?

Dr. EISENBERG. Yes. It is essential, in fact, that that be done. I think one of the most important contributions in the field of health services research in the past decade has been to help us to move from simply measuring years to measuring the value and the quality of those years. There is research going on that helps us to use generic measures of quality and disease-specific or condition-specific measures of quality. This research is very early, but early results are extremely helpful. In fact, in this study of lung volume reduction surgery, there are quality of life measures that are being introduced into the outcomes assessment.

Chairman THOMAS. And was that generally accepted? Was it a fight to get it in? What occurred around it?

Dr. LENFANT. Mr. Chairman, I am really so pleased to hear you ask that question, which is an extremely important one. The specific trial which is before us today, as Dr. Eisenberg mentioned, includes quality of life measures. They were very easily accepted by the participants, because everybody knows they are such an important element in this kind of medicine.

I should tell you that in many of the clinical trials which are sponsored by the National Institutes of Health, quality of life is a standard measure. So it is taken into consideration and we look for that very, very carefully.

Chairman THOMAS. Well, I am very much concerned because if we cannot get the kind of computerized patient records for outcomes research on a comparison of various procedures and the cost effectiveness of it, at the very least, I think we should begin to get an age-based reaction to those very procedures, because without a solid statistical base for making decisions, if, in fact, withholding of medical services because of a quality of life factor and a cost-effectiveness one is one that is supposed to be made on the floor of the House or the floor of the Senate, I can assure you it is not going to be done. The most effective way would be between the physician and the patient and the determination of whether or not it is going to be paid for and the benefit to the patient, notwith-

standing the desire to do it, from a solid statistical base of whether or not they are ever going to get out of bed, whether or not they are ever going to carry on any kind of normal lifestyle procedure.

That, to me, is very critical in moving forward in a comprehensive counseling structure, not only for those who will receive the benefit and their loved ones but those who pay, as well.

Mr. VLADECK. Absolutely.

Chairman THOMAS. Thank you very much.

Mr. VLADECK. Thank you.

Dr. EISENBERG. Thank you.

Dr. LENFANT. Thank you, Mr. Chairman.

Chairman THOMAS. There was no controversy surrounding any of these subject matters, and that is just various minor adjustments. My assumption is this next panel might indicate that there is a bit more controversy than would otherwise be the case.

The second panel consists of Dr. David Gollaher, president and chief executive officer, California Healthcare Institute in La Jolla; Ted R. Mannen, executive vice president of Health Industry Manufacturers Association; Dr. David Sheridan, Medicare medical director of the Palmetto Government Benefits Administrators of Blue Cross and Blue Shield of South Carolina for the Blue Cross and Blue Shield Association; and Dr. Joel Cooper, who is chairman of Thoracic Surgery, Washington University School of Medicine in St. Louis, Missouri.

I would tell each of you that any written testimony you have will be made a part of the record, and you can address the panel in any way you see fit for the time that you have. Why do we not start with Dr. Gollaher and then just move across the panel.

STATEMENT OF DAVID L. GOLLAHER, PH.D., PRESIDENT AND CHIEF EXECUTIVE OFFICER, CALIFORNIA HEALTHCARE INSTITUTE, LA JOLLA, CALIFORNIA

Mr. GOLLAHER. Thank you very much, Mr. Chairman, distinguished Members. I am glad to see your Subcommittee addressing what I think is a central, core issue in American health care for the Medicare Program and for the rest of health care, as well.

I am the president of the California Healthcare Institute, which is a research and policy organization based in California that represents some 150 companies and universities who have one thing in common, which is their commitment to medical innovation, either discovering or developing for the marketplace inventions that solve unmet medical needs—AIDS, Alzheimer's, cardiovascular disease, breast cancer, and so many other diseases.

California is a laboratory for biomedical innovation, but it is also a living laboratory for health care delivery experimentation, the most advanced managed care market in the world.

Let me just say, by way of personal disclosure, that I currently represent companies and universities that are engaged in biomedical innovation, but I spent some part of my life as an executive of the Scripps Clinic and Research Foundation. When I joined Scripps in 1985, we had 5,000 HMO enrollees. When I left in 1990–91, we had 85,000. It was part of my responsibility when I was there to manage managed care and I have the scars to prove it. It

was a most painful and difficult transition, yet it reflects a lot of what is going on within American health care.

I must also say, as part of my experience, we brought up Scripps' first, and one of San Diego County's first, Medicare HMOs, and my parents were enrollees number one and number two in that program. So watching them progress over the past several years and use a great many health care services has given a living quality to my own experience as someone who deals with health care policy.

Now, managed care poses a novel set of concerns about medical technologies and patients' access to state-of-the-art medical treatment. For all the reasons that other witnesses have described, and particularly the financial incentives that are inherent in capitation, an ugly word, but the idea in which a set fee is paid for all health care services for a group of people, no matter how many or how few they actually use.

It is one thing for physicians in the old fee-for-service system to try something that just might work when the procedure is going to be paid for by an insurance company, and it is quite another when the costs come out of the pockets of the physicians themselves. The attitudinal shift is enormous, as one might expect.

People, patients, are aware of this and aware that economic incentives influence all of our decisions, physicians as well as the rest of us, and there has naturally arisen a widespread fear, which has been inflated by stories on the front pages of the media, that many of the most advanced, most promising diagnostics, medicines, and medical devices might be unavailable simply because it is in the financial interest of an HMO or an HMO doctor not to use that technology.

With respect to Medicare coverage, this would seem to be a comparatively easier problem to solve than in the private sector, because, as Mr. Vladeck pointed out earlier, medical necessity is at the heart of the Medicare contract from the beginning and managed care plans, as well as others, are obligated to provide medically necessary or medically appropriate services.

The difficulty, though, of course, is that medical necessity and medical appropriateness are notoriously imprecise and ill-defined terms. In an ideal world, a patient would appear before a physician with distinct, intelligible symptoms. The physician would make a definite diagnosis, select a scientifically proven therapeutic intervention, and, finally, observe an outcome.

Unfortunately, the real world of health care does not resemble this model at all. As the eminent scientist and physician Louis Thomas once said, "Medicine is the youngest science," and by this he meant that our ability to apply scientific methods to clinical care, above all, to connect a specific outcome to a specific therapeutic intervention, that science is still in its infancy.

The main reason for this is not that we lack talented scientists but that variations in the way doctors practice medicine, combined with enormous differences in individual patients, even though we use the same word for their disease, limit our ability to generalize about what is best, about what works and what does not work.

So technologies are the essential tools of medicine, but in the clinic, the art of medicine consists in the physicians choosing the

best tool among many alternatives in light of his or her own experience, the patient's individual condition and individual preferences.

As Dr. Eisenberg mentioned, benign prostatic hyperplasia, BPH, which is an enlargement of the prostate that affects millions of men covered by Medicare, the symptoms range widely for this disorder, from mildly irritating to severe, and there are literally dozens of treatments that are now available, ranging from surgery to radiation therapy to a new generation of drugs for this disorder. But in many cases, men, with their doctors' approval, may delay any treatment at all, watching to see whether their symptoms get better or worse, living with their symptoms.

In the case of BPH, as for so many other conditions, there is not one medically appropriate technology but many, and it seems to me that Medicare's proper role in this confusing muddle is to make sure physicians and patients are free to choose the approach or the technology that suits them best. Certainly, Medicare should not at this point of our state of knowledge be in the business of dictating one marginal technology over the other. The Government is poorly equipped to practice medicine.

But on the other hand, with the Government paying the bill, we share a collective interest in demanding that Medicare get its best value for the money, and that is something that is clearly the responsibility of the agencies that manage this important program.

In California during the past year, in order to help managed care manage better, two important things have happened, and I can address those quickly.

The first is that much pressure within the State legislature has gone to strengthen disclosure and to make disclosure a dynamic process so that patients know what the rules are, what standards apply to the treatment decisions, practice guidelines, and so forth. This is essential, partly to gain the confidence of patients and physicians in the system and partly to make sure that patients have access to the full range of medical knowledge about not only their treatment and condition but about the practice standards and approach that physicians are using to their disease, which leads to the second point, having to do with the timely impartial appeals process.

This has already been mentioned, but in California, we, in conjunction with the California Medical Association, successfully sponsored legislation last year to establish a third-party appeals process in cases in which patients are denied coverage on the basis of a technology being considered experimental or investigational. Patients are smarter than ever before about their conditions and their diseases and are much more demanding of leading-edge technologies, and they need the right to seek those technologies where they think they may apply.

Finally, I would like to make a brief comment about the role of Federal agencies in evaluating technologies with respect to Medicare coverage. Within our industry, the producers of medical technologies, the main experience has been with the Food and Drug Administration, which does set a gold standard for determining the safety and effectiveness of drugs and devices but also is often viewed as overly bureaucratic and overly slow in getting new medicines and new medical devices to market.

To expand the role of the FDA or any other agency into this important area of cost effectiveness, of technology assessment with respect to insurance coverage, threatens to create exactly the choke point, exactly the type of barrier to new technologies that people most fear in HMOs.

Thank you.

[The prepared statement follows:]

Statement of David L. Gollaher, Ph.D., President and Chief Executive Officer, California Healthcare Institute, La Jolla, California

Mr. Chairman and Distinguished Members:

My name is David Gollaher, and I'm the President of the California Healthcare Institute, a research and public policy organization representing some 150 companies and universities with one thing in common: a deep commitment to medical innovation. Patients hope and expect that companies like the ones we represent will soon offer solutions to our greatest unmet medical needs—AIDS, Alzheimer's, cardiovascular disease, breast cancer, and so many others.

Today health care in California, and across the nation, is the midst of a profound transformation. Generally speaking, this transformation stems from the desire of those pay most of the nation's health care bills—namely, employers and governments—to rein in their budgets. In many cases, the mechanism they've chosen to control costs is managed care. While there are many species of managed care, they have one characteristic in common. Essentially managed care shifts the financial risk for medical care away from payers and patients and places it squarely on health care providers, mainly doctors, hospitals and so forth. The best known managed care companies are health maintenance organizations, HMOs, who typically pay physicians and hospitals a set monthly amount to take care of a group of patients, no matter how little or how much medical care they actually use.

Managed care poses a novel set of concerns about medical technologies and patients' access to state-of-the art medical treatment. In the Medicare program, as in the private sector, the HMO system of fixed Or "capitated" reimbursement creates clear and present economic incentives to restrict the use of medical technologies, particularly if the technology is costly and its potential benefit to the patient is uncertain. It's one thing for physicians to try something that just might work when the procedure will be paid for by an insurance company. It's quite another when the costs must be directly absorbed by the physicians themselves.

People's common sense awareness that economic incentives influence physicians' decisions has given rise to widespread fear, inflated by stories in the media, that some of the most advanced, most promising diagnostics, medicines, and medical devices might be unavailable simply because it is in the financial interest of an HMO or an HMO doctor not to use them.

With respect to Medicare coverage, this might seem to be an easy problem to address through regulation. After all, the heart of Medicare insurance is the principle that the program will pay for services deemed "medically necessary" or "medically appropriate." And HMOs that contract with Medicare are legally bound to provide such services.

The difficulty, however, is that the concepts of medical necessity and medical appropriateness are notoriously imprecise and ill-defined. In an ideal world, a patient would appear before a physician with distinct, intelligible symptoms. The physician would make a definite diagnosis, select a scientifically proven therapeutic intervention, and finally observe a clear result.

Unfortunately the real world of health care scarcely resembles this model. The eminent physician and scientist Lewis Thomas once called medicine "the youngest science." And by this he meant that our ability to apply the scientific method to clinical care—above all, to connect a particular treatment precisely to a particular result was, and still is, in its infancy.

The main reason for this is not that we lack talented scientists, but that variations in the way different doctors practice medicine, combined with enormous differences in individual patients, limit our ability to generalize about what is best, about what works and what doesn't. In the clinic, technologies are the essential tools of medicine. The art of medicine consists in a physician's choosing the best tool in light of his or her own experience, the patient's individual condition and, importantly, the patient's individual preferences.

Take benign prostatic hyperplasia, for example. BPH is an enlargement of the prostate that affects millions of men covered by Medicare. The symptoms range widely, from mildly irritating to severe. And there are a number of treatments: sur-

gery, radiation, a new generation of drugs. In many cases men, with their doctors' approval, may delay any treatment at all, watching to see whether their symptoms get better or worse. In the instance of BPH, as for so many conditions, there is not one medically appropriate technology, but several.

It seems to me that Medicare's proper role is to ensure that physicians and patients are free to chose the approach, or the technology, that suits them best. Certainly it should not be to dictate one technology over another. Government is poorly equipped to practice medicine. On the other hand, when government is paying the bill, we all share a collective interest in demanding that Medicare get the best possible value for money.

One of the consequences of managed care has been increasing pressure to define value in health care, and to employ various management techniques—carrots and sticks—to encourage physicians and patients to use high value technologies. As managed care organizations have grown in size and complexity they have spent millions of dollars trying to sort out those technologies that provide the best value, and have adopted practice guidelines to promote their use. The drive for consistency is a natural byproduct of management. And so long as the drive for consistency is linked to providing better quality medical care, it benefits everyone.

The best managed care organizations understand that medical quality and cost control are not incompatible. Doing what is best for the patient, even if it is expensive in the short run, leads to better outcomes, higher levels of patient satisfaction, better morale on the part of physicians.

At the state level, there have been a variety of approaches to using the regulatory process to make managed care organizations accountable for the way they make clinical decision, the incentives they use to shape physician behavior, and the way they communicate with patients. In California, the nation's most advanced laboratory when it comes to managed care, two important principles have emerged.

1. Disclosure is crucially important. The standards, practice guidelines, coverage limitations, and so forth, that managed care organizations use should not be a black box. Patients and their doctors should know what's covered and what's available. Moreover, disclosure should be active not passive. That is, the rules should not be fine print, but communicated dynamically, when they are relevant to treatment decisions.

2. A timely appeals process for coverage denials is essential. Confidence depends on a sense of fairness and due process. In California last year our group, along with the California Medical Association, successfully sponsored legislation to establish a third-party appeals process in cases in which patients are denied coverage on the basis of a medical technology's being considered experimental.

In regard to leading-edge technologies, it seems fitting that the federal government increase its commitment to clinical research, just as it sponsors basic life sciences research and graduate medical education. The recent debate over the value of routine mammography in women under 50 year old to screen for breast cancer is a perfect example of a crucial medical question that can only be fully addressed with sufficient federal data and federal sponsorship.

By the same token, the Food and Drug Administration performs a unique, essential function in reviewing new technologies for safety and efficacy. From the perspective of Medicare, FDA approval (which is in fact a very high standard) should be all that is necessary for a product to take its place among the many tools available to doctors and their patients. The application of the tool constitutes the practice of medicine, that is, a matter to be decided within the context of the physician-patient relationship.

In this budget season, it is worth noting that the FDA has made strides of late, becoming more efficient in the process of reviewing new drugs and devices. It remains critically important that Congress pass legislation this year to modernize the Agency and appropriate full funding so that the Agency retains the people necessary to do the work. Since the FDA has been unable to meet its statutory review times for new technologies, it seems wholly inappropriate for the Agency to expand its mission into major new areas, for example, analyzing the cost-effectiveness of drugs and devices. This task is better left to the market.

While there is an enormous amount of work to be done to improve our understanding of costs and benefits, of the outcomes of different clinical interventions, and of patient preferences, the producers of new medical technologies rightly worry about a large, programmatic incursion of government agencies into these areas. They worry because their experience of the FDA is all too often an experience of an unwieldy, unresponsive bureaucracy, seemingly indifferent to the urgency of speeding new technologies to waiting patients. As much as we need for the youngest science to advance, we fear that the wrong kind of government involvement could create new barriers to innovation. Indeed, the interposition of new federal agencies

into the process of evaluating medical technologies in regard to Medicare coverage threatens to recreate exactly the kinds of obstacles for patient access to new drugs and medical devices that people fear in HMOs.

Mrs. JOHNSON [presiding]. Thank you very much.
Mr. Mannen.

STATEMENT OF TED R. MANNEN, EXECUTIVE VICE PRESIDENT, HEALTH CARE SYSTEMS, HEALTH INDUSTRY MANUFACTURERS ASSOCIATION

Mr. MANNEN. I am Ted Mannen, an executive vice president of HIMA, the Health Industry Manufacturers Association. HIMA represents companies that make medical devices, diagnostic products, and health care information systems, and we very much appreciate the chance to testify today. We commend the Subcommittee for bringing attention to this important issue of Medicare coverage.

You have our written statement in which we suggest ways for modernizing and improving the Medicare coverage process. Today, now that I have reviewed some of the other statements, I thought I might make my oral comments a little more targeted.

First, we agree with the point made in HCFA's statement that Medicare should make coverage decisions and modify them whenever necessary to reflect new findings and data. However, I would like to add our own perspective to that, and I would like to use a specific example to show you how this attempt to keep up with changing information plays out in practice.

The example I would like to use is a technology called magnetic resonance angiography, or MRA. MRA allows physicians, in effect, to see the blood as it flows through the body. This helps medical professionals make better decisions.

In 1995 Medicare covered MRA on a very limited basis. In August 1996, based on new information, HCFA said it had decided to expand coverage of MRA to the lower limbs of the body, and the purpose of that is to allow judgments to be made as to whether Medicare beneficiaries need to undergo bypass surgery. Yet today, 8 months after HCFA said it was expanding coverage, not one Medicare patient has benefited from this purported expansion. And that is because Medicare has not given its local contractors the required instructions to actually implement this change.

So please understand, we are talking here about a technology that HCFA agrees should be covered, yet it is not covered. And it has been 8 months now and beneficiaries of Medicare have not had access to this particular technology.

The second area is technology assessment. HCFA says the coverage process now includes technology assessments that are state of the art. HIMA certainly supports sound technology assessments, but our concern is that the assessments done for Medicare coverage often operate to delay patient access to beneficial technologies.

For example, according to an HHS study, the technology assessment on shock wave lithotripsy for kidney stones took 560 days, the assessment on implantable chemotherapy infusion pumps took 1,272 days, and the assessment on magnetic resonance imaging

took 1,288 days. I should point out that these time periods are for the technology assessments alone. They do not include the additional time required to actually make the coverage decision.

Finally, let me just say a word about so-called category B devices. Now, these are certain devices that are used in FDA-approved clinical trials. These are devices for which, as HCFA puts it, the fundamental issues of safety and effectiveness have already been resolved. In its statement, HCFA says that category B devices are eligible for Medicare coverage while they are being studied for incremental risk.

In our statement, we describe a new and very promising laser treatment called transmyocardial revascularization, or TMR. This procedure involves a category B device, but contrary to HCFA's statement, this device is not eligible for Medicare coverage. Instead, HCFA has told its local contractors that they are not allowed to determine whether to reimburse for this procedure.

This decision was made by HCFA's Technology Advisory Committee, or TAC, and I should just point out that TAC meetings are closed, the issues under review at the meetings are not disclosed in advance, and the decisions made at the meetings are barely disclosed afterward. If you look at the Web site of HCFA, you will find that the minutes on that site for the TAC meetings are at least several months out of date, and I think they have missed at least a couple of meetings.

It is this process that HCFA uses to make decisions on treatments like TMR, and it is treatments like TMR where the rubber really meets the road.

I want to emphasize that we are not talking here about abstractions. We are talking about real Medicare patients. In the case of TMR, these are patients that have end-stage heart disease. These are patients for whom all other treatment have failed. They face pain, repeated hospitalization, and the threat of death. Yet with TMR, if they had access to it, they would face the prospect of life.

So for these and other reasons, we believe that the Medicare coverage process should be improved and modernized along the lines we suggest in our written statement. We stand ready to work with the Subcommittee and with HCFA to do this, and we very much appreciate the chance to be here today.

[The prepared statement follows:]

Statement of Ted R. Mannen, Executive Vice President, Health Care Systems, Health Industry Manufacturers Association

Mr. Chairman, my name is Ted Mannen. I am Executive Vice President, Health Care Systems, for the Health Industry Manufacturers Association, known as "HIMA."

HIMA is composed of some 700 manufacturers of medical devices, diagnostic products, and health information systems. While HIMA represents many of the industry's largest firms, our membership is principally made up of smaller companies—the kinds of companies that frequently incubate new technologies.

HIMA very much appreciates the opportunity to testify today. In our testimony, we would like to leave you with three points:

First: "Quality"—a watchword in today's health care debate—cannot be a reality in Medicare unless there is a sound process for covering new technologies and medical procedures.

Second: The current Medicare coverage process could be significantly improved and modernized so that decisions—and patient access to new technology—occur in a more timely fashion.

Third: The growth of managed care within Medicare presents new questions concerning the coverage process, chief among them: How well does the process assure quality—through timely access to medical advances—for Medicare's managed care enrollees?

Relationship Between Coverage and Quality

"Quality" is a word we often hear in health care these days. We hear it in connection with gag clauses, access to emergency rooms and specialists, and so-called "drive-by deliveries"—important issues, all.

But at its core "quality" must surely include something more. It must surely include the kinds of tools that medical professionals have available to help them help their Medicare patients. And the "portal" through which these tools must pass, as they make their route to professionals and patients, is the Medicare coverage process. For it is this process in which Medicare decides whether a technology will be eligible to be used in the program at all.

If the coverage portal is not functioning properly—if approval is slow or wrongly denied—then patients will not have access to beneficial new techniques that might improve or save their lives. This result is not an abstraction; it translates, tangibly and concretely, into a heart attack that is not treated, into a cancer that is not prevented, into pain that is not alleviated. And in each of these cases, Mr. Chairman, a direct blow has been struck against quality care.

For these reasons, then, genuine quality in Medicare requires a smoothly functioning coverage process. This process—however technical and arcane it may sound—deserves our ingenuity, our creativity, and our energy.

Today's hearing shows the Subcommittee's concern about this topic. We thank you for that, and we applaud you for your leadership.

Modernizing Medicare Coverage

Let me now outline some of the elements that we believe are essential for assuring the kind of Medicare coverage process that yields quality care.

Timeliness of Decision Making

We believe that one of the most important ingredients is timeliness—how promptly the Medicare program makes coverage decisions affecting patient access to medical technologies.

Timeliness, in turn, can hinge on how efficiently the process itself functions. The mechanics of the coverage process involve the Health Care Financing Administration, its local and regional contractors, and, in some cases, the Agency for Health Care Policy & Research.

"Mechanics" and "process" may sound mundane, but let me assure you that their implications for beneficiaries are not. For example, for national coverage decisions involving a formal technology assessment, the assessment alone can take an average of more than two years. During this period, many local Medicare contractors deny payment for the technology under review.

Similarly, the process for making coverage decisions at the local and regional levels can be unclear, unpredictable, and slow. For example, some regional decisions on coverage of durable medical equipment can take three years.

In sum, then, the process itself can affect timeliness and patient access to medical advances.

"Experimental" and "Standard" Care

Timeliness is also a function of the criteria and assumptions that underlie coverage decisions. One such assumption goes to the very heart of patient access to technology: the assumed distinction between "experimental" and "standard" care.

Historically, these terms have had significant meaning in coverage policy—a "line in the sand," if you will, that had important consequences for patients. A technology on the "standard" side of the line was covered by a patient's insurance; a technology on the "experimental" side was not. This was a decision tree with only two branches—and they were rigid branches, at that.

We believe that this way of thinking is fast on its way out and that a new, modern view of technology is beginning to take hold. Let me illustrate by giving you three brief examples from the recent literature:

• University of Texas professor Stanley Reiser likens medical technologies to trains that shuttle "in an oscillating motion . . . between standard and experimental stations." As a way to address this fact, he outlines a new zone of hybrid technology that he calls "crossover therapy." ("Criteria for Standard Versus Experimental Therapy," Health Affairs, Summer 1994.)

• Earl Steinberg, Sean Tunis, and David Shapiro cite "the need to balance several legitimate but conflicting social objectives" in making decisions on experimental care. They advocate coverage for certain kinds of experimental care, which they call "special-priority" technologies. ("Insurance Coverage for Experimental Technologies," Health Affairs, Winter 1995.)

• Associate HCFA Administrator Kathleen Buto points out that "HCFA could consider changes that will make promising therapies available earlier and lead to better data on use and patient outcomes." As possible approaches, she suggests consideration of "limited coverage" and a clinical research fund. ("How Can Medicare Keep Pace With Cutting-Edge Technology?" Health Affairs, Summer 1994. Views expressed were those of author; no endorsement by HCFA was intended or should be inferred.)

What we take from these examples is a new, more modern middle ground in which the question is no longer: "On which side of the experimental/standard line does a technology fall?" Instead, the question is becoming: "How do we best identify the uses of technology that are appropriate?"

This more modern appreciation of clinical reality can greatly improve quality of care. For it suggests a more sophisticated view of how the timing of coverage decisions can affect the timeliness of patient access to medical advances.

Coverage Policy Consistent with Device Innovation

The timing of decisions—identifying when in a technology's development to decide coverage—is especially important for device technology. That's because of the special nature of device innovation. Development of devices is an iterative, interactive process in which "revolutions" are the direct result of incremental "evolutions."

In cardiovascular therapy, for example, there has been a series of continual improvements, from vascular grafts and the first pacemakers in the 1950s; to mechanical heart valves in the 1960s; to, today, implantable defibrillators that help keep alive patients at risk for sudden cardiac death. While each of these advances is dramatic in its own right, none would have been possible without earlier, iterative evolutions in the technology.

A coverage process timed to discourage technology early in its development cycle—before its full uses can be foreseen—will short-circuit quality and short-change patients. Instead, we need a practical means for efficiently introducing device technologies and encouraging their appropriate use. This will allow us to innovate toward even better technologies—and even higher quality care—tomorrow.

Medicare Should Lead

How do these points apply to Medicare?

First, instead of distinctions like "experimental" and "standard" care, we need a more discerning approach to coverage—one that takes into account the appropriate use of technology in individual cases.

"[J]oint doctor-patient decisionmaking," the Physician Payment Review Commission (PPRC) noted in its 1995 Annual Report to Congress, "can better tailor treatment to individual patients . . . than can coverage decisions." Indeed, much of the current debate on health care quality proceeds from the premise that physicians and patients, working together, are the most reliable guardians of individual health and well-being. We need to inject more of this sort of realism into the Medicare coverage process.

Second, our policies should bridge the "experimental"/"standard" gap to provide earlier patient access to promising medical advances. We believe that many private health plans may be taking the lead in doing this.

For example, PPRC, in its 1995 Annual Report to Congress, noted that private insurance plans "have often paid the clinical costs associated with . . . devices when used under an investigational device exemption (IDE), in effect deeming them acceptable therapy."

At the very time PPRC was publishing this report, HCFA officials were saying (incorrectly) that these same IDE devices (and the associated clinical costs) were not eligible for Medicare coverage. HCFA has since published a regulation on this subject, and we want to acknowledge HCFA's efforts and especially applaud your leadership on this issue, Mr. Chairman. But our point is that at a time when private insurance plans were already making investigational technologies available to their patients, Medicare was trying to argue that its beneficiaries shouldn't have access to these very same kinds of technologies.

We also want to bring to the Subcommittee's attention a 1994 survey on private insurance coverage, specifically coverage by private managed care plans. This survey found that many of these plans cover experimental procedures if they are considered to be very promising in treating life-threatening disease. (See Steinberg,

Tunis, Shapiro, "Insurance Coverage for Experimental Technologies," Health Affairs, Winter 1995.) More recently, state laws, as well as proposals at both the state and federal levels, increasingly provide greater flexibility in making new medical advances available to the patients who need them.

And so, for all these reasons, we believe that the traditional view of coverage is being overtaken by a new wave of thinking. Unfortunately, Medicare seems, at best, a reluctant participant in this process of change.

For example, one new and very promising laser treatment is called transmyocardial revascularization—or "TMR." This technology is intended for patients with end-stage heart disease. For these patients, all other treatments have failed, leaving them only angina pain, repeated hospitalizations, and the threat of death. Yet, with TMR, they face the prospect of life.

One 61-year-old patient had suffered five heart attacks in less than 10 years and had undergone numerous surgical interventions with little success. Yet today, after TMR, he is not only alive but well enough to walk his two very large dogs—each an energetic, 85-pounder.

Mr. Chairman, these are the kinds of cases in which Medicare has the chance to be a leader in providing quality care. Unfortunately, in the case of TMR, Medicare has declined to cover this technology for the foreseeable future. For patients with end-stage heart disease, that may not be soon enough.

We recommend that Medicare more aggressively embrace the new thinking on coverage decision making. This will improve the timeliness of patient access to medical advances and raise the quality of care in the Medicare program.

Medicare Managed Care

The final issue we would like to address today is the coverage process within Medicare managed care plans. And here we come not with a policy prescription but with a set of questions.

Our overall point is that there is much that is not known about the coverage process within the managed care part of Medicare. This part of Medicare is growing rapidly. And so it behooves us all to learn more about the access to technology that Medicare's managed care enrollees can expect.

I should make clear that I am not referring here to categories of benefits—such as prescription drugs and preventive care—that a managed care plan may choose make available to its Medicare enrollees. Instead, I'm talking about the actual technologies needed to implement the available benefits. For example, to which technologies will a beneficiary have access during an inpatient hospital stay?

Our preliminary examination suggests that the law gives little guidance on this kind of question or, more generally, on the criteria that managed plans should follow in making coverage decisions. HCFA's current practice is simply to oversee managed care plans in the same general, managerial fashion it oversees the traditional insurance carriers that serve as Medicare contractors.

Therefore, as you consider Medicare coverage, we urge you to take into account the growing role of managed care. We urge you to examine such questions as these:

- How should Medicare managed care plans make coverage decisions?
- In what fashion should plans be accountable for their decisions?
- Does access to technology differ significantly, depending on whether a beneficiary is in the managed care or fee-for-service parts of Medicare?

Again, Mr. Chairman, we raise these questions not to advocate a particular policy. We raise them to identify an area that requires more information and attention.

Conclusion

Let me conclude where I began by saying that a key to Medicare quality is a sound coverage process. And the key to a sound coverage process is timely access to beneficial technologies for professionals and their patients.

Mr. Chairman, we thank you for the opportunity to present our perspective. We urge you to continue to examine the Medicare coverage process through additional hearings and other forums. Now and in the future, we welcome the opportunity to work with the Subcommittee and with HCFA to address the important, intertwined issues of coverage and quality.

Mrs. Johnson. Thank you very much.

Dr. Sheridan.

STATEMENT OF DAVID SHERIDAN, M.D., MEDICARE MEDICAL DIRECTOR, PALMETTO GOVERNMENT BENEFITS ADMINISTRATORS, BLUE CROSS AND BLUE SHIELD OF SOUTH CAROLINA, BLUE CROSS AND BLUE SHIELD ASSOCIATION

Dr. SHERIDAN. Thank you. Mr. Chairman and Members of the Subcommittee, I am Dr. David Sheridan, medical director of the Medicare fee-for-service operations at Blue Cross and Blue Shield of South Carolina, testifying today on behalf of the Blue Cross and Blue Shield Association.

Our plan has served as a Medicare contractor since the program began in 1997. This year we will process about 34 million claims and pay about $10 billion in Medicare benefits.

I think you can see that I wear two hats today. First of all, I represent an organization that provides technology assessment as well as an organization that uses technology assessment.

The point of my discussion today is that we believe the Medicare Program is developing an approach to medical policy that carefully and skillfully balances local medical decisionmaking in the context of a national program. It also kept pace with changing medical knowledge and practices and it has addressed emerging needs in a timely and creative manner.

My testimony today will address three issues. First of all, How are Medicare coverage and medical policy decisions developed? Number two, how are these policies implemented? And number three, the problems Medicare contractors anticipate in the next year because of the potential funding cutbacks proposed by the administration.

First, let me talk about the development of medical policies. We make coverage decisions at the local level for individual patients and determine whether to pay for a particular service and, oftentimes, how to apply national coverage guidelines that come down from HCFA. The foundation of our medical policy development is flexibility because medical practice has to respond to the unique and changing facets of each patient. The continuing advance in medical science inevitably means that standards written yesterday will not necessarily be appropriate today or tomorrow.

Historically, it was accepted that all standards for medical practice should be local because most of the medical practice was really locally based. Over time, the Medicare Program has developed national policies where there is consensus on the medical appropriateness of a specific treatment or procedure.

National policies are developed in two ways. First of all, national policies are developed by HCFA, using state-of-the-art evaluation technologies conducted by other Federal agencies, by the Blue Cross and Blue Shield Association's Technology Evaluation Center, which I will talk about in 1 minute, and others. In addition, Congress also provides detailed specifications on certain Medicare coverage policies, for example, on screening mammographies.

In the absence of national policies, however, Medicare contractors develop local policies, using a process set by HCFA that requires extensive consultation with the local providers and beneficiaries. I might add here that in terms of the range of all medical procedures, the number of national coverage decisions is really very

small, and so there is a fair amount of discretion at the local level about which procedures to apply policies to. But local contractors do not necessarily try to apply medical policies to every procedure that is in their framework, either. There are really a very small number of procedures overall that have any medical policy in the fee-for-service Medicare Program.

Now, in addition to this consultation process that we develop local policies in, HCFA has also developed a recent initiative to increase the consistency across the Nation for contractors and they have done that by encouraging local work groups of Medicare medical directors to develop model local medical review policies. Three years ago when I started in this job, I think we had about 5 work groups and now we are up to about 25 different work group areas to develop medical policies in.

While these are not officially national policy, they do serve as models and peer standards for all contractors. Most importantly, though, as contractors take these model policies and submit them to their own carrier advisory committee as part of the process of local medical policy development, we have a chance to test these policies at a local level, refine them, and return the model policies changes to the national level. So as a result, the policies that we finally disseminate are based on broad-based support by the medical community in the States that we work in.

The bottom line is that all of these technologies are developed from the scientific literature and other technology assessments that we have available. A major source of these technology assessments is the Blue Cross and Blue Shield Association's Technology Evaluation Center, referred to as the TEC program. This program is now the largest of its kind in the world, with its assessments being used by Blue Cross and Blue Shield plans, in the Federal Government through Medicare and CHAMPUS, and other insurers who subscribe to the service. Plans use the TEC evaluations to develop their own medical policies, including guidelines for the conditions under which a procedure will be covered.

I would like to move on to the second point in terms of implementation. After we have developed these policies, the real work begins because we must apply these to specific patient care situations. Contractor medical review activities are targeted to assure that the appropriate payments are made and to detect and prevent fraud and abuse.

HCFA anticipates savings of almost $2 billion from applying these policies in 1997. In South Carolina, this translates to part B savings, which I am most familiar with, of about $33 million in prepayment savings and $3 million in postpayment savings. That really translates into about $28 savings for each dollar spent on medical review activities.

Without a timely implementation of local medical review policy, millions of dollars more would be wasted through fraudulent and medically unnecessary services, so I emphasize here that the local contractor can make more timely decisions about policies and implement them.

I want to touch on the third point, funding shortages. I do want to express our concern and the association's concern about the administration's proposed 1998 budget in that it is entirely inad-

equate to handle the increasing claims volume. Before detailing these problems, I want to express the association's appreciation, and mine most of all, for the Subcommittee's action last year to provide a stable funding stream for contractor payment safeguard activities.

Unfortunately, the administration is proposing a 17-percent cut in the amount paid to process each claim, a reduction three to six times as large as any reductions experienced in this decade. This will result in the deterioration of a whole variety of contractor activities, including beneficiary and provider services, fraud and abuse detection, and so forth because a lot of our claims review and detection of these situations really comes from our first-line claims processing operations.

In summary, I would just suggest that Medicare policy development is in evolution. Currently, policy development combines the timeliness of local development with the consistency of model and national policies. Local policies foster grassroots support for scientifically sound policies unachievable by national pronouncements.

Thank you.

[The prepared statement follows:]

Statement of David Sheridan, M.D., Medicare Medical Director, Palmetto Government Benefits Administrators, Blue Cross and Blue Shield of South Carolina, Blue Cross and Blue Shield Association

Mr. Chairman and members of the subcommittee, I am Dr. David Sheridan, the Medical Director of the Medicare Operations of Blue Cross and Blue Shield of South Carolina. On behalf of the 59 Blue Cross and Blue Shield Plans, I welcome this opportunity to comment on the important issue of medical policy and the Medicare program. Few issues are as technically complex or involve such rapid change as the development and administration of medical policy.

Since the inception of the Medicare program, Blue Cross and Blue Shield of South Carolina has been the Medicare fiscal intermediary and carrier in South Carolina, responsible for making payments to hospitals, nursing homes, physicians, clinical labs, and other individual providers.

In addition, Blue Cross and Blue Shield of South Carolina serves as a regional Medicare contractor for four categories of services:

1. A regional home health agency intermediary one of eight such contractors in the country—responsible for making payments to home health agencies in 13 states.
2. A durable medical equipment regional carrier (DMERC) responsible for making payments to durable medical equipment suppliers in 14 states.
3. The Medicare National Supplier Clearinghouse.
4. The Medicare National Statistical Analysis Durable Medical Equipment Regional Carrier.

In fiscal year 1997, Blue Cross and Blue Shield of South Carolina will process about 34 million claims and pay about $10 billion in Medicare benefits to health care providers and beneficiaries.

Collectively, Blue Cross and Blue Shield Plans process about 90 percent of Medicare Part A claims and about two-thirds of all Part B claims.

We believe that the Medicare program has developed an approach to medical policy that carefully and skillfully balances local medical decision making within the context of a national program. It has also kept pace with changing practices and knowledge in this area. And, it has addressed emerging needs in a timely, creative manner.

The question that gives rise to this hearing is one of the most complex in the entire field of medical policy. It concerns the variation in coverage policies among regions or areas. Specifically, the question is how it is that a carrier may approve coverage of a given service in one area while another carrier may disapprove coverage of the same service in a different area. Are such differences evidence that the "system" of medical policy making is "broken"?

The short answer to this question is a firm "no." Such differences are, in fact, both unavoidable and essential. Without them, medical policy would never advance. It would never be able to incorporate new scientific knowledge. The test of whether the system works is whether such differences are reasonable, and whether the sys-

tem includes mechanisms to identify such differences and, if necessary, resolve them on a timely basis.

My testimony will focus on four areas:

1. Development of Medicare Coverage and Medical Policy Decisions.
2. Innovative Leadership in Medical Policy of the Blue Cross and Blue Shield Association's Technology Evaluation Center.
3. Implementation of Coverage and Policy Decisions.
4. Funding Shortages in the Administration's FY 1998 Budget Proposal for Medicare Administration.

Development of Medicare Coverage and Medical Policy Decisions

The Medicare statute is fairly general in describing what is covered under Medicare. The law requires coverage of broad categories of benefits (e.g., hospital, physician services, etc.), but does not generally specify which individual items and services are covered.

The law prohibits Medicare payment for services that are not "medically necessary" for diagnosing or treating a medical illness. In providing guidance to its Medicare contractors, HCFA has indicated that payments will be approved for medical services that are "safe and effective, not experimental or investigational, and appropriate."

Medicare contractors apply these guidelines, using a combination of national and local criteria. Medicare has been able to develop and apply flexible medical policies that are responsive to local needs and circumstances while working within a national program. We believe that the successful administration of Medicare must include three essential elements:

- Flexible standards. Successful medical policy cannot be rigid. Standards must be sufficiently flexible to accommodate advances in medical knowledge and the unique medical condition of each patient.
- Responsive to local needs and circumstances. The implementation of medical policy must be able to accommodate wide differences in the capacity of local health care delivery systems.
- Consistent national policy where consensus exists on medical appropriateness of a specific procedure or treatment. While medical policy must not be rigid, neither can it allow wide disparities in coverage that are in conflict with solid clinical evidence.

The foundation of medical policy is flexible standards. Medical practice must respond to the unique and changing facts of every patient. To make matters even more complicated, the knowledge that is the basis of medical practice is constantly evolving. The continuing advance of medical science inevitably means that standards written yesterday will not necessarily be appropriate today.

It should be noted that medical policy guides the determination of whether a given service or procedure will be covered. It does not replace the judgment of the practicing physician in deciding on an appropriate course of treatment. Medical policy strives to guide coverage decisions without creating unnecessary rigidity. The goal of medical policy is to make sure that beneficiaries receive the care that will most effectively and efficiently meet their needs. Sometimes medical policy results in coverage of services that are newly accepted medical practices. At other times, medical policy results in the denial of coverage for inappropriate or unnecessary care. In every case, the ultimate criterion is whether the care that is covered is clinically appropriate given the patient-specific medical condition and circumstances.

Historically, it was accepted that standards for medical practice should be local. Over time, the Medicare program has developed national policies where there is a consensus on the medical appropriateness of a specific treatment or procedure.

The most significant challenge in the ongoing development, maintenance, and implementation of medical policy is the relentless advance of medical science. A technological breakthrough is not immediately adopted. It may be weeks, months, or even years, before a new treatment is widely accepted. A new procedure is likely to win acceptance sooner in the communities with close ties to the center where the breakthrough was first achieved. And it is likely that national consensus on a new standard for treatment will require months or even years to develop.

This means that in some communities the local standard will be in advance of any national policy. This is almost inevitable in the ever evolving advances in medicine.

Over the recent years, HCFA has made significant efforts to develop more consistent national medical policy standards. When HCFA has developed national medical policy standards, they are to be used by Medicare contractors . Even under these national policies, it is important to realize that there is some flexibility to tailor

these policies to specific patients' needs. In the absence of any national medical policy standards, the local contractor is responsible for developing appropriate medical policies using a process specified by HCFA.

National medical policies are developed in several ways:

- HCFA develops guidelines for national medical policy and related coverage policy and publishes these for contractors, providers, and beneficiaries. In developing these guidelines, HCFA relies on state-of-the-art evaluations conducted by federal agencies and the Blue Cross and Blue Shield Association's Technology Evaluation Center program (described later), and consults extensively with Medicare contractors, providers, and beneficiaries.
- Occasionally, legislation is enacted which provides detailed specificity on Medicare coverage policies (e.g., screening mammography).
- Finally, HCFA has recently begun a process to increase national consistency in decision making through the development of local model medical review policies by workgroups of Medicare Contractor Medical Directors. These workgroups identify specific issues to address each year; evaluate the variations in policies among the contractors; and work to develop a proposed national model in consultation with appropriate providers. HCFA reviews these proposed model medical policies and if they do not conflict with HCFA's national coverage decisions, the work group releases the model to the local contractors for consideration. While the carriers are not required to use these models, they are generally adopted at the local level.

In the absence of national policy, each contractor makes its own decisions for new technologies in consultation with their staff and the local medical community. These local policies are made based on evidence from the scientific literature or on generally accepted practices in the local medical community.

Some carriers use BCBSA's technology assessments (discussed in the next section) as the foundation for local decisions; others develop their own based on internal committees that perform technology assessments and make coverage recommendations. HCFA requires contractors to follow a process in making these local decisions:

- First, the contractor must identify the need for a new policy and verify that a national medical policy has not been set in the area.
- Medicare contractor Medical Directors (physicians) then develop a proposal after reviewing the scientific literature and seeking advice from health professionals and experts in the field.
- Comments on draft policies are requested from Carrier Advisory Committees local committees that each carrier is required to establish. These committees are comprised of medical specialties, other health care professionals, and beneficiaries.
- These proposed policies are required to be made public and are published prior to implementation.

Innovative Leadership in Medical Policy BCBSA's TEC Program

The Blue Cross and Blue Shield Association (BCBSA) has been a pioneer in the development of technology evaluation.

In 1985, BCBSA established a comprehensive technology assessment program called the Technology Evaluation Center (TEC) that is now used by Blue Cross and Blue Shield Plans, the federal government, including Medicare and CHAMPUS, and other insurers who subscribe to the service. TEC is now the largest program of its kind in the world.

This program does not establish medical policy nor recommends whether technologies should be considered eligible for reimbursement. Instead, it summarizes and synthesizes the best existing scientific evidence to determine the safety and efficacy of new and emerging health technologies. The findings are provided to all independent Blue Cross and Blue Shield Member Plans, and, on a subscription basis, to other interested organizations managed care companies, insurers, health systems and others.

The Technology Evaluation Center is one of the nation's leading technology assessment organizations, having issued more than 250 assessments since 1985 on a variety of medical interventions. By design, the TEC program focuses on the "hard questions." It takes up questions about coverage for treatments, drugs, devices, procedures, and biological products using the following criteria:

1. The technology must have final approval from the appropriate government regulatory bodies.
2. The scientific evidence must permit conclusions about the effect of the technology on health outcomes.
3. The technology must improve the net health outcome.
4. The technology must be as beneficial as any established alternatives.
5. The improvement must be attainable outside the investigational settings.

Assessments are conducted by TEC staff, including physicians and research scientists, who are supported by professionals in the areas of pharmacology, nursing, biostatistics, epidemiology and library science.

The staff work is reviewed by the BCBSA's Medical Advisory Panel—a panel of nationally recognized experts in technology assessment, clinical research and clinical practice. A majority of the members are independent medical experts with no affiliation to health care payers.

In 1993, TEC began to work collaboratively with Kaiser Permanente on the assessment program with the goal of furthering research and publication of credible technology evaluation. About 35 assessments are published each year.

Plans use the TEC evaluations to develop their own medical policies, including guidelines for the conditions under which a procedure will be covered, the information that must be provided to support a coverage determination, and determining the specific providers that have the experience and credentials necessary to perform the procedures.

Implementation of Coverage and Policy Decisions

After development of coverage and medical policy decisions, the real work of using the policies to guide specific decisions begins. This process involves review by specially trained nurses and other clinical staff, review by physicians, and opportunities through which practicing physicians and members can appeal initial unfavorable determinations. At every stage, the concern of BCBS Plans is to make sure that the beneficiary's treatment is justified on clinical grounds.

Contractor medical review activities fall into two major areas: 1) prepayment review; and 2) postpayment audits.

1) Prepayment Review

All carriers screen claims before payment to detect potential utilization problems, such as unnecessarily intense or frequent care. Claims may be suspended by computer screens for more thorough investigation and for review of medical necessity. These screens are based primarily on specific procedures, frequency of services, and physician-specific data accumulated from a history of previously processed services.

There are misconceptions about the use of computer screens. Carriers use such screens as a cost-effective tool to determine which services should be reviewed. Claims which are not triggered by these screens are automatically paid.

At Blue Cross and Blue Shield of South Carolina, physicians are integral at each step of the medical review process and lead reviews of the complex, questionable cases and difficult to resolve payment denial appeals.

HCFA requires all carriers to use national screens. In addition, carriers are allowed to set their own screens to focus on problems a carrier has identified in its service area. These problems can vary significantly from carrier to carrier. This year, our Plan used additional carrier initiated screens.

2) Postpayment Review

Postpayment review is intended to monitor the Medicare claims experience of all providers and services in a region. We focus on high dollar and frequently performed services. Aggregated data is subjected to statistical analysis in order to identify physicians or suppliers whose utilization patterns differ substantially from their peers. By profiling physician and supplier services, we can identify patterns of overutilization, excessive testing and fraud and abuse. Examples of provider profiles include: the type of office visits (e.g., intermediate or complex) billed by providers; the rate primary care physicians refer patients to specialists; the number of tests and x-rays ordered by physicians. Profiles are done for individual providers and then are compared to the rates for the provider's peers. Actions that are taken include provider education of acceptable norms and information on billing processes and practices, payment recovery, and local medical review policy supported by prepayment screens.

We also emphasize an informational and educational approach to our activities. As part of this educational function, we notify doctors when their pattern of claim submissions is substantially different from that of their peers. Each year, we also undertake a specialized focused review of a specific service that is frequently performed. Last year, we concentrated on payments for prostrate cancer treatment, anesthesia services, and chemotherapy treatment.

These in-depth reviews can last several months and include an analysis of claims trends, patient surveys, consultant review of medical records and/or discussion of our findings with the provider.

In addition to the general educational efforts undertaken in the postpayment review process, we also publish monthly newsletters for all Medicare providers. This newsletter is used to notify the provider community of the ever-changing Medicare rules before they are implemented.

These medical review activities result in significant savings to the Medicare program. In total, HCFA anticipates spending $152 million in 1997 for this function with savings of $1.9 billion, a 12 to 1 return. At Blue Cross and Blue Shield of South Carolina, we expect that we will spend $7 million on these activities this year, and return $200 million in savings to Medicare, a 28 to 1 return on the investment.

Funding Shortages in the Administration's FY 1998 Budget Proposal for Medicare Contractors

We are very appreciative that this Committee took action last year to provide a stable funding stream for medical review activities and other payment safeguard initiatives.

As you know, funding for these activities have deteriorated over the past decade and has not allowed Medicare Contractors to perform the kind of reviews that are essential to detect fraud and abuse and prevent unnecessary payments. This new funding should allow us to reverse this trend and to improve our efforts.

We do remained concerned that the Administration's recommended Medicare Contractor funding level for 1998 is entirely inadequate to handle the almost 900 million claims expected to be received in 1998, 4.3 percent more claims than processed in 1997. Particularly problematic is the proposal to cut the amount paid to process each Medicare claim by approximately 17 percent in 1998, compared to 1997.

The impact of this cut would be:

- Deterioration in beneficiary and provider services, including paying claims on time, responding promptly to beneficiary and provider inquiries and appeals for reconsideration of initial payment decisions.
- Inability to combat fraud and abuse effectively, since claims processing activities serve as the first line of defense in detecting suspicious claims and unnecessary payments.
- The exit of more Medicare Contractors from the program, because of the inability to manage the workload effectively within this proposed budget.
- Future problems in Medicare's ability to implement the changes that are necessary to preserve the program for future beneficiaries.

Adequate, stable funding levels are essential to handle Medicare's constantly increasing workload, maintain quality service to Medicare beneficiaries and providers, pay claims within the time frames established by Congress and prevent fraud abuse and overpayments.

Conclusion

In closing, I would emphasize that the challenge of developing and implementing coverage policy is inherently complex and difficult. Not only does the state of medical science change continuously, but the rate at which new advances in medicine are adopted into accepted practice varies among regions. National coverage policies must provide guidance without producing an undesirable rigidity.

Medicare has developed and continues to refine a good system for meeting this challenge. The substantial flexibility that is granted to local administrators allows for appropriate variation in coverage among communities and promotes the dissemination of new knowledge. The appeals mechanism prevents local variations in coverage policy from producing inequities among communities or preventing beneficiaries from gaining access to state of the art medical treatment. And the system of national medical policy standards administered by HCFA provides a mechanism for identifying the need for and disseminating national coverage policies to guide local medical review.

Mrs. Johnson. Thank you very much, Dr. Sheridan.
Dr. Cooper.

STATEMENT OF JOEL D. COOPER, M.D., JOSEPH C. BANCROFT PROFESSOR; AND HEAD OF THORACIC SURGERY, WASHINGTON UNIVERSITY SCHOOL OF MEDICINE, ST. LOUIS, MISSOURI

Dr. COOPER. Thank you, Mrs. Johnson and Mr. McCrery. It is an honor to testify before you today, and I have respectfully submitted my written statement for the record.

In 1983 my colleagues and I performed the world's first successful lung transplant, a procedure which is now highly successful for certain patients who are terminally disabled from emphysema, cystic fibrosis, and some other lung diseases. Four years ago, we developed an operation for improving the breathing capacity and the quality of life for certain patients disabled from severe emphysema and we termed that operation the lung volume reduction surgery.

Following the introduction of each of these procedures, transplant and volume reduction, I have spent a number of years seeking coverage and reimbursement from both private and governmental health care providers so that patients in need could have access to these procedures.

Historically, HCFA has lagged far behind the private sector when making coverage decisions. For example, HCFA finally enunciated a coverage policy for lung transplant in 1995, almost 10 years after private insurers began covering this procedure. HCFA announced coverage policy for liver transplantation in April 1991, 8 years after the majority of insurers provided coverage, and there has been the same lag for heart transplants, heart-lung transplants, and others.

There is overwhelming scientific evidence that the lung volume reduction procedure offers improvement not available by any other means other than lung transplantation. Unfortunately, following our introduction of this procedure, there was a rapid proliferation of surgical procedures for emphysema, including some which, frankly, were unsubstantiated or inappropriately applied.

The Medicare system was faced with a major challenge in terms of assessment and coverage of this new procedure. In November 1995, a request for information and comment on the procedure was published in the "Federal Register" to assist HCFA in determining Medicare coverage policy. To our surprise, only 2 weeks later, Medicare coverage for the procedure was abruptly suspended.

HCFA has announced its intention to use the results of a joint NIH–HCFA trial to reassess its coverage policy. The trial requires Medicare patients who have exhausted all alternative therapies to be assigned, essentially by the flip of a coin, to either have the operation or, for comparison purposes, to continue the therapy already proven ineffective. The trial, which has not yet begun, is scheduled to last 5 to 7 years and will be limited to a very small number of patients who then have to undergo randomization, effectively denying most Medicare patients coverage for this procedure for yet many more years.

To date, all other health care providers with whom we have dealt, amounting to more than 75 in total, Federal, State, VA, government workers, private insurance, whatever you would like, have approved the procedure. Independent assessments have already been carried out by a number of organizations, including the na-

tional Blue Cross and Blue Shield organization, Aetna, Kaiser Permanente, and recently the Health Technology Advisory Committee of the Minnesota Health Care Commission. All have concluded that the operation provides benefits not otherwise achievable and meets the coverage requirements under specified circumstances.

While many questions remain unanswered, such as the duration of benefit, these can be scientifically addressed without denying coverage to the type of patients for whom clear benefits have already been established.

I direct your attention to the appendices in my testimony identifying over 60 medical articles available to HCFA, if it so chooses to review them. Two-thirds have been published since HCFA's December 1995 noncoverage decision and the other third are in press and available to HCFA if they ask for them.

I do support a HCFA-sponsored study with the NIH to encourage the further development and scientific analysis of the volume reduction procedure. However, this trial should not be used as a substitute for HCFA's responsibility to provide a mechanism for timely coverage based on available scientific information.

My recommendation is what is termed coverage with conditions, meaning Medicare should pay for the operation as long as patient selection is appropriate, in limited numbers of medical centers with careful, ongoing accumulation of data so that we can learn the long-term effects of the operation and how to best apply it. This is the same mechanism which HCFA finally established for coverage of lung transplants.

HCFA continues to insist that there is no evidence for the procedure being efficacious for any group of patients, and rather than summarize the scientific data from 60 manuscripts, I would like, with permission, to show you a 1-minute video of a patient before and 2 years after the procedure so you can see for yourself the type of difference the operation can make.

[A videotape was shown.]

Dr. COOPER. This is a patient from Texas, aged 59, whose lung capacity was reduced to 9 percent of predicted. You see him on the left before the operation and 2 years later on the right. Before the operation, he could not take a bath, he could not get dressed by himself, he could not go out of the house, and in our judgment, he had about 2 months to live. You can see on the left the tremendous effort that he has to make just to breathe, even though all he is doing is sitting there.

He has oxygen on him, which he required continuously. He is wasted. He has gained 30 pounds since the operation. You can see he is not a happy camper. He requires oxygen continuously, and this video, without going into a lot of detail, shows that he is using muscles that we normally use to move our arms and head around, called accessory muscles, he is using them preoperatively to try to pull up on his rib cage a little bit to squeeze a little bit more air into his chest because it is so distended from the emphysema process. So he is using those muscles as a last attempt to try to squeeze a little bit of air into his enormously distended chest.

There he is on the treadmill 2 years later. He is now taking care of his cattle farm in Texas and does not need oxygen.

That is sufficient for the video. It is anecdotal, but I can assure you that it is not unrepresentative, and it does offend me a bit when HCFA insists that there is no evidence of efficacy as the excuse for another 5- to 7-year delay in providing coverage.

Thank you very much.

[The prepared statement and attachments follow:]

Statement of Joel D. Cooper, M.D., Joseph C. Bancroft Professor; and Head of Thoracic Surgery, Washington University School of Medicine, St. Louis, Missouri

HCFA'S PROSPECTIVE RANDOMIZED TRIAL FOR LUNG VOLUME REDUCTION SURGERY: THE EMBODIMENT OF ITS NEW MEDICARE COVERAGE POLICY

Mr. Chairman and Members of the Subcommittee, my name is Joel Cooper, M.D., and I am The Joseph C. Bancroft Professor and Head of Thoracic Surgery at the Washington University School of Medicine at Barnes-Jewish Hospital in St. Louis, Missouri. I am pleased to appear before you today to discuss the status of the Health Care Financing Administration's (HCFA's) Medicare coverage policy and how it has been applied to two surgical procedures which I have helped develop.

In November of 1983, my colleagues and I at the University of Toronto were fortunate to achieve the first ever successful human lung transplant. This followed 20 years of unsuccessful attempts throughout the world, since Dr. James Hardy, at the University of Mississippi, first attempted a lung transplant in 1963. Our initial patient, terminally ill from a condition called pulmonary fibrosis, was able to resume a normal life, and return to full time employment for over six years before his death in 1990. This initial success, first reported in the New England Journal of Medicine in 1986, was followed by numerous other successes over the years, and lung transplantation has now been well established as an important treatment for many patients with end stage lung disease such as emphysema, cystic fibrosis, and others. In 1988, I returned home to the United States, to develop a center for chest surgery, including lung transplantation, at Washington University School of Medicine and Barnes-Jewish Hospital. Since that time, our cardiothoracic service has performed over 330 adult and 133 pediatric lung transplants.

In 1993, based upon experience with lung transplantation in patients with emphysema, and reports of earlier work from the University of Maryland in the 1950's, we developed a palliative operation designed to improve the quality of life for certain highly selected patients suffering from severe emphysema. We have termed this procedure lung volume reduction surgery or LVRS. By removing non-functioning overinflated portions of emphysematous lungs, the fixed hyperinflation of the chest is reduced, and a more normal breathing pattern established. The medical data collected thus far, much of which is published, or is to be published in peer reviewed journals, objectively demonstrates that LVRS measurably improves lung capacity and exercise performance, greatly alleviates the symptoms of severe breathlessness, and significantly improves the subjectively-measured quality of life for these disabled individuals.

As a result of my role in developing lung transplantation and lung volume reduction surgery as innovative therapies, I was recently named the third recipient of the Jacobson Innovation Award by the American College of Surgeons. The two previous recipients were Dr. Francois Dubouis, who was given the award for the development of laparoscopic surgical techniques, and the second was Dr. Thomas Starzl, for his pioneering work which made liver transplantation a reality. Both of the procedures, lung transplantation and lung volume reduction surgery, offer benefit not achievable by any other means to severely disabled individuals suffering from end stage emphysema. As we all know, however, these health benefits cannot be provided unless someone is willing to pay for the procedures. As a result, over the years, I have spent considerable time and effort to secure funding of these procedures for patients seeking these new interventions. This has involved the combination of scientific validation of the procedures, accumulation of experience from other centers, and often legal challenges to private and governmental health care providers. Acting as a patient advocate in these matters, I have tried to insure that our limited health care dollars are appropriately spent on worthwhile procedures, and that new procedures such as these are subject to careful evaluation and ongoing assessment.

Two years after the first successful lung transplant, in November of 1985, we performed the first successful lung transplant on an American citizen, a gentleman who now lives in California and continues to enjoy good health. After a series of appeals, his transplant was covered by his private insurer. In January of 1987, we performed

a successful bilateral lung transplant on a woman from Boston who was insured by Blue Cross Blue Shield of Massachusetts. After we made a presentation at their technology assessment committee, Blue Cross Blue Shield of Massachusetts accepted both unilateral and bilateral lung transplants as a covered service. Our patient continues to enjoy a normal life, more than 10 years later.

To assist the Subcommittee in understanding, and perhaps defining HCFA's role in making Medicare coverage and reimbursement decisions, I would like to focus on the experience I have had with Medicare coverage for patients undergoing lung transplantation, and more recently lung volume reduction surgery. HCFA finally announced a national coverage policy for lung transplantation in February of 1995, over 11 years after our initial success and 10 years after initial provision of coverage by a private insurer. It should be noted that the National Blue Cross Blue Shield Technology Assessment Committee, following its own evaluation, accepted lung transplantation as an effective treatment in 1991, and Aetna Insurance provided coverage as of January 1990.

It is useful to review the history of Medicare coverage of various organ transplants over the years, and to compare the time lag of Medicare coverage to that of private insurers. The acceptance of organ transplantation as a reasonable and effective method of treating end-stage disease was embodied as a statutory provision of the Social Security Act in 1973, at which time benefits for kidney transplants were provided by HCFA. Liver transplants, pioneered by Dr. Starzl in the 1960's and 70's, achieved a high rate of success following the development of improved immunosuppressive medications in the early 1980's. HCFA declared adult liver transplants to be a covered service in April of 1991 (which led to retroactive coverage to March 1990). This was over five years after the National Blue Cross Blue Shield organization approved liver transplants and eight years after coverage was provided by Aetna. Heart transplants, pioneered by Dr. Norman Shumway at Stanford University in the late 1960's and 1970's, also achieved a high degree of success by the early 1980's. HCFA provided Medicare coverage in April of 1987 (retroactive to October 1986) over four years after private insurers provided coverage. The combined heart-lung transplant, also pioneered at Stanford University in the early 1980's, was funded by private insurers in the United States by 1985. In fact, I performed a successful heart-lung transplant in Toronto, on a young woman from Chicago, in 1985, who is still alive today. Her insurance company covered the cost of her procedure at that time. Yet it was not until February of 1995, 10 years later, that Medicare coverage for the combined heart-lung transplant was provided. In April of 1987, this procedure was specifically listed as a procedure which was not covered by Medicare, an action which prevents Medicare contractors throughout the country from making an independent assessment of cases on an individual basis, providing coverage where it is deemed appropriate.

Since returning to the United States in 1988, I have learned more than I cared to about the delays, inconsistency, and often discriminatory aspects of Medicare coverage for newer treatments. I have learned that most Medicare benefits are not determined by a national coverage policy, but by over 40 individual contractors, consisting of Medicare intermediaries who oversee hospital costs under Medicare Part A, and carriers who oversee professional fees under Medicare Part B. One advantage of this system is that the contractors can readily assess cases, on an individual basis, if necessary, and provide the services if they deem them "reasonable and necessary" as required by Federal law. Furthermore, rulings by the contractors are subject to the judicial process and can be appealed to an administrative law judge. It is my understanding that in this situation, the administrative law judge has the authority to "look behind" the evaluation process used by the contractor, and decide whether or not the evaluation withstands further scrutiny. Without a national non-coverage decision by HCFA on lung transplantation, we were able to utilize the local flexibility in the system to secure federal funding for our lung transplant recipients who were Medicare-dependent beneficiaries. A disadvantage of the decentralized process for determining coverage (which can only occur in the absence of a national non-coverage decision) is the potential for inconsistency in the provision of services to Medicare beneficiaries in different parts of the country. In theory, however, the potential inconsistency is resolved over time as the medical data is developed.

When a national coverage, or non-coverage determination is made by Medicare, this decision is binding on all Medicare contractors. While this produces a consistent policy, there are serious problems which arise, when attempting to appeal a non-coverage determination. It is my understanding that in such circumstances, the courts cannot review the process of evaluation but must accept the Medicare non-coverage determination as binding. Furthermore, the appeals process for the patient, denied a service under a national non-coverage policy, is intimidating in the extreme.

Several years ago, a potential lung transplant recipient sought the aid of his congressman to obtain Medicare funding for his lung transplant. Medicare's response to the congressman noted that, at the time, lung transplants were not a covered service, while heart transplants were. His letter went on to note that in the case of a combined heart-lung transplant (a single transplant procedure in which the heart and lungs are left with their intimate attachments to each other intact and inserted as a whole package) Medicare would pay only for those parts of the operation and care related to the heart portion of the transplant, but not those portions related to the lung!

Another heart rending result of inconsistent Medicare coverage is related to the funding of immunosuppressive drugs following transplantation. These drugs must be taken for the rest of the recipient's life in order to prevent rejection of the transplanted organ. Costs for the drugs may exceed $10,000 a year, a sum which many, if not most Medicare beneficiaries find impossible to afford. Medicare's provision of these drugs has been grudging, at best. Initially, immunosuppressive drugs were provided for only the first year. Later this was extended to 18 months, then to 24 months, and more recently to 30 months. Patients, for whom organ transplants have been provided under the Medicare system, desperately sought ways of securing the drugs necessary to keep them alive. An underground support system was developed across the country. Family members of transplant recipients who died provided unused immunosuppressive drugs to other transplant recipients. In some cases, this has been facilitated by religious or other organizations. The anxiety created in transplant recipients by not having drug coverage, and the demeaning nature of the behind scenes struggle to secure these life saving drugs, has for me been one of the saddest examples of deficiencies in our health care coverage system.

Throughout this century surgeons have proposed numerous procedures in an attempt to alleviate the distressing symptoms of severe breathlessness and the debility associated with end-stage emphysema. These procedures have included such operations as cutting across ribs to improve the movement of the rib cage, collapsing part of the chest to reduce the size of the lung, paralyzing the diaphragm, and cutting various nerves which supply innervation to the lung. Some have been met with skepticism while others were enthusiastically endorsed, but virtually all have been discarded by the physicians when careful scientific scrutiny failed to demonstrate objective efficacy.

It is well recognized that focusing attention and support on patients with a chronic illness may, for a time, make them feel better, even if there is no objectively measurable improvement. Only lung transplantation, and another rarely applicable procedure called bullectomy, have stood the test of time and have provided objective as well as subjective benefit. Therefore, in 1993, when we developed a new procedure for selected patients with severe emphysema, we at Washington University, established careful selection criteria, and collected numerous objective and subjective measurements of efficacy on all patients undergoing this procedure. Furthermore, before offering this procedure, all patients were subject to a rigorous program of optimum alternative management including medication, nutritional support, psychological support, and a vigorous program of exercise rehabilitation. By this means, the maximum achievable benefit by alternative therapy was first obtained before final consideration for surgery. This insured that the decision to operate was made only after all other known treatments had been exhausted, that the patient was in the optimum preoperative condition so as to reduce the risks of the operation, and furthermore, provided a scientifically valid basis of evaluating the operation, by comparing the postoperative results with the baseline measurements obtained after intensive medical therapy.

We initially reported our preliminary findings, in the first 20 patients, at the annual meeting ohoracic Surgery, in New York City, in April 1994. This was published in January of 1995 in the Journal of Thoracic and Cardiovascular Surgery. Our presentation, and subsequent publication, generated a great deal of excitement in the pulmonary community. The operation was considered an exciting new advance, offering significant benefit to a group of patients for whom conventional therapy had failed. It was emphasized that this operation was a palliative one, that the duration of benefit was yet to be determined, and that strict guidelines for selection of patients was required. Furthermore, the successful introduction of the operation at our center was made possible, in part, by the presence of a highly experienced and diverse team of surgeons, physicians, anesthetists, respiratory therapists, physiotherapists, nurses, nutritionists, etc., who had cared for hundreds of patients with severe lung disease undergoing lung transplantation. At that time, notwithstanding the as yet undefined role of the procedure and the definite risks associated with performing major bilateral lung surgery on severely breathless, oxygen dependent patients, application of the procedure spread rapidly.

Emphysema, one of the leading causes of death in this country, taking 17,303 lives per year according to NHLBI's 1995 statistics, is an extremely debilitating chronic disease. Many of these patients can no longer take a shower, may require an hour and a half to get dressed, can no longer walk stairs, can no longer travel, and rarely can get out of the house. Of the patients whom we have selected for surgery, more than half required continuous use of oxygen, and over 90% required oxygen at some time during the day. Approximately one-quarter used a wheelchair and most, when warned of the potential risks of the procedure, have a standard reply ... "Doctor my life is over .... I have nothing to lose".

Unfortunately, it must be admitted, that the rapid proliferation of surgical procedures for emphysema included procedures which were unsubstantiated, involved poor or perhaps inappropriate patient selection, and were performed at some institutions without the necessary background, expertise and support to achieve optimum results. Clearly, the Medicare system was faced with a major challenge in terms of assessment and coverage of LVRS. Whereas, with organ transplantation, the vast majority of recipients are not Medicare beneficiaries, such is not the case with emphysema surgery. Approximately 50% of candidates for this procedure, in our experience, have been Medicare beneficiaries. Because of the large number of emphysema sufferers in this country, and the fact that Medicare is the predominant insurer of these individuals, the issue of coverage for Medicare patients demands timely consideration.

I must acknowledge the inability of the medical profession on its own to insure that this new intervention was introduced in all instances in a careful, controlled, responsible fashion, and applied only at selected institutions with careful, prospective, complete, ongoing analysis of results. Coverage for Medicare beneficiaries was initially provided by some, but not all Medicare contractors. However, because of the controversy surrounding the procedure, and exaggerated claims of benefit for other, unsubstantiated procedures, LVRS became one of the 10 to 20 procedures each year which Medicare subjects to a centralized process of technology assessment. The purpose of such an assessment is to determine whether services are, (or will continue to be) "reasonable and necessary" for Medicare coverage purposes. In November of 1995 therefore, the Agency for Health Care Policy and Research published a notice of assessment oy and effectiveness" of lung volume reduction surgery. The notice, with a submission deadline of February 13, 1996, specifically indicated that the assessment was for purposes of advising Medicare on LVRS coverage. However two weeks later, without benefit of the requested data or assessment by the AHCPR, HCFA announced a national coverage decision to its carriers, not to cover LVRS beginning January 1, 1996. In March 1996, HCFA's technology assessment committee (TAC) met and decided to continue its non-coverage decision. I have expressed to HCFA's Bureau of Policy Development my concern at the glaring inaccuracies, misrepresentations, and incomplete data presented to the TAC committee, as reflected in its minutes. I was recently informed, by a member of the Bureau of Policy Development, that in fact, even if such inaccuracies or misrepresentations had been present, they were of no practical significance, since the bureau had "already made up its mind" prior to the TAC meeting, and considered the TAC meeting as one for dissemination of information only. Please see Appendix A for a complete chronology HCFA's and NIH's actions regarding LVRS.

In May of 1996, HCFA and the National Institutes of Health announced the joint sponsorship of a seven year prospective randomized study to gather data on the safety and effectiveness of LVRS. The outline of the proposal is shown in Appendix B. As one of the 18 principal investigators selected to participate in the study, I am aware that patient enrollment is intended to begin in the summer or fall of 1997, and at least a five year study is envisioned, in which a limited number of patients will be enrolled. Furthermore, in order to have access to Medicare coverage for the procedure, patients must consent to be randomized to either conventional medical therapy, or to medical therapy plus the lung volume reduction procedure. It is the current position of Medicare that insufficient data exists to substantiate the benefit of LVRS. Hence, limiting the number of Medicare beneficiaries who can enter the study, and requiring that half of those be denied access to the procedure to serve as a "control", or natural history group, is, in their opinion, ethically defensible. Thus, from the effective date of Medicare's non-coverage decision on January 1, 1996, six to seven years will go by before the results of the HCFA sponsored NIH study are expected to be available.

The situation for non-Medicare patients, however, is quite different. A number of independent assessments of this procedure have been carried out by various organizations, insurance companies, and HMOs. The National Blue Cross Blue Shield organization found the procedure to meet their criteria for coverage some time ago, as did the Aetna insurance company and Kaiser Permanente, an HMO. To date, vir-

tually all health providers with whom we have dealt, amounting to more than 75 in all, have provided coverage for their beneficiaries at our institution. Respected for its thoroughness and objectivity, the Health Technology Advisory Committee of the Minnesota Health Care Commission in their February 1997 report on LVRS, concluded after review of the available literature and consultation with experts in the field that:

I. Short term effectiveness of six to 18 months has been demonstrated;

II. The benefits of the surgery appear to outweigh the harm;

III Mortality rates are at an acceptable level of a major pulmonary/thoracic procedure;

IV. It appears that on a short term basis, health care costs for a patient after LVRS are less than for other patients before LVRS. For example, patients do not need long term oxygen therapy.

The complete HTAC report is given in Appendix C. The independent assessment organization, ECRI, in its report of May 1996, concluded that data at the time showed the treatment appeared to "offer short term benefits for carefully selected patients when the procedure is performed by experienced surgeons. Data on the long term benefits of the procedure are not available."

Numerous professional organizations have endorsed the procedure under appropriate circumstances. This includes the American College of Chest Physicians, the American Thoracic Society, and the American Association of Respiratory Care. In November of 1995, the CPT editorial panel of the American Medical Association undertook an evaluation of LVRS. The panel accepted a new CPT code for the lung volume reduction procedure as previously reported by our center.

Coverage at the present time is provided not only by all major insurers, but by many Medicare HMO providers as well, even though not obligated to do so under their contractual arrangements with Medicare. This procedure is also covered and reimbursed at Veterans Administration Hospitals, by state Medicaid providers, and, I am told, by U.S. Government insurance for postal workers, and others.

Presumably, because of the controversy surrounding the procedure, and the anticipation of a long and drawn out process before Medicare coverage is provided, the Congress, through Public Law 104–208, signed by the President on September 30, 1996, required HCFA to analyze all the available data and report its recommendations regarding reimbursement for LVRS. Congress set a January 1, 1997 deadline. The conference report accompanying the law required Secretary Shalala to describe "the method and schedule for restoring Medicare coverage of lung volume reduction surgery." I understand HCFA failed to meet the January 1 deadline and asked for an extension to provide the Report "on or before April 1, 1997." To the best of my knowledge, HCFA has not responded.

It should be noted that HCFA's decision to continue its non-coverage policy is based upon the health care technology assessment which they requested from AHCPR. That report, prepared early in 1996, was based on a far more limited data base and experience than is now available. A partial list of publications on LVRS, now available, is listed in Appendix D. The AHPCR report, published a year ago, concluded that it "cannot reasonably be concluded at this time that objective data permits a logical and scientifically defensible conclusion regarding the risks and benefit of LVRS as currently provided." The report cited the large variations in patient selection criteria, the nature of the procedures performed, and most importantly, lack of complete accurate follow up data at many centers. A significant shortcoming of the AHCPR study was that it grouped data from different procedures. If it had separated out the data, as now required by Public Law 104–208, LVRS results may have been much more discernible and favorable. The report thus concluded that "notwithstanding, the data suggests that as-yet an undefinable proportion of patients with severe COPD may have realized some benefit from the procedure. If the surgery could be accomplished without undue morbidity or mortality, a prospective trial of LVRS under uniform protocol requirements with comprehensive long term postoperative follow-up data is both ethically supportable and scientifically essential." Specifically, AHCPR's assessment did not recommend that access to the procedure be limited or that randomization be imposed as a prerequisite for access to LVRS.

Serious issues now confront us regarding the process by which Medicare coverage is provided to its beneficiaries for new and developing technologies and procedures. First, Medicare has never succeeded in publishing a description of their process for making coverage decisions. As per the settlement of the Jameson v. Bowen case in 1987, HCFA agreed to publish a description of the process and criteria that it uses to make Medicare coverage decisions, including decisions as to whether new procedures are covered, based upon a finding of reasonableness and necessity and/or safety and effectiveness. On January 30, 1989 a proposed rule was published in the Fed-

eral Register, but, a final Medicare coverage policy has not been published. And according to a recent news report quoting a high-ranking HCFA official, a final rule "may never be published in any form."

In fairness, I must acknowledge that in my opinion, Medicare initially saved lives by suspending payment for the lung volume reduction procedure, because of some of the abuse which existed, given some questionable procedures being conducted at less than qualified centers, with exaggerated claims of benefit which were unsubstantiated. I believe that HCFA recognized the value of the procedure when properly applied at qualified centers, but was unwilling or unable to restrict its application to insure careful, ongoing, prospective evaluation by which the ultimate role and value of the procedure could be assessed. Having no such mechanism, HCFA turned to the National Institutes of Health to conduct a scientific trial. This permitted NIH to select centers, taking the political heat off of HCFA. An NIH trial may indeed be one of the best methods for scientifically evaluating and validating a new medical procedure over the long term, but is not, in my opinion, the most appropriate method for making a coverage decision for LVRS, which can be offered to beneficiaries under controlled circumstances, as recommended by the AHCPR assessment.

The proposed study jointly sponsored by HCFA and NIH, calls for very limited access to the procedure, and is, in essence rationing. Furthermore, to be consistent with HCFA's position that clear cut benefit from the procedure has not been documented, the NIH trial incorporated randomization as a requirement, namely, that each appropriate candidate would have to agree to be assigned, essentially by the flip of a coin, to either have the operation or be denied the operation for a number of years. Since Medicare-dependent beneficiaries have no alternative recourse to obtaining the procedure, unlike these who can afford to pay for it out of their own pockets, or those fortunate to have insurance or HMO coverage, this provision has the effect of discriminating against Medicare-dependent patients as subjects for a randomized trial which is ethically highly questionable, in my opinion. In order to participate in the trial, each of the 18 centers is now being asked by HCFA and NIH to adopt a position of "clinical equipoise," namely, to tell patients who have exhausted all current alternative therapies, that there is no evidence that the operation is any better than continuing their medical management. Yet none of the 18 centers chosen, including our own, has seen the need to randomize patients, and has provided the operation routinely to appropriately selected candidates. In essence, we have the financing mechanism, HCFA, imposing its judgement on the physicians, telling us that our medical judgement, what is best for the patient, does not count.

The prospect of requiring Medicare patients to comply with a long term randomized trial, when most other individuals have coverage for the procedure, creates a political and ethical dilemma. In an attempt to avoid this, HCFA, and NIH, took two further highly controversial actions. The first was to insist that all centers participating in the NIH trial, require all non-Medicare patients, or self pay individuals, to agree to randomization as a requirement for being treated at that center. Thus, we were told, that if a patient, covered, for example, by a Blue Cross Blue Shield provider, sought the surgery at our center, and was unwilling to adhere to randomization with the possibility of denial of surgery for a period of years, then we were to instruct the patient that we could not provide the operation and they would have to seek treatment at another center. Since it is highly unlikely that any covered patient or self pay individual seeking the operation would agree to such randomization, this in effect denies such individuals access to treatment at the very centers chosen as most qualified to perform the surgery.

The second action involved NIH and HCFA officials making one or more conference phone calls to private insurance providers, in an attempt to persuade the companies to withhold LVRS coverage from their beneficiaries unless the beneficiaries agreed to participate in the NIH trial. This, in effect, would have required the insurance companies to reverse their established position based upon their own assessment. To the best of my knowledge, none of the companies approached has agreed to reverse its previous coverage policy. Both of these actions, however, reflect upon HCFA's effort to dictate how physicians practice medicine in the private sector, which appears to be well beyond the scope of HCFA's jurisdiction or authority. To summarize, with the lung volume reduction procedure, as with many previous innovations, Medicare has been among the last to provide coverage for its beneficiaries. The reasons and motives behind this are difficult to ascertain. Mr. Bruce Vladek has insisted that it is not a money issue. Perhaps it is not a money issue for HCFA, but it certainly is a serious money issue for Medicare beneficiaries, most of whom cannot afford to pay privately for uncovered services. If it is indeed a money issue, then we should in fact admit it, and acknowledge that the Medicare system, for whatever reasons, is unable to provide the same level of care currently provided by most private insurers. If it is not a money issue then the process of ap-

proval needs to be fixed to make it less discriminatory against, and more accessible to Medicare beneficiaries. I propose the following:

1. Whenever a new or promising treatment or technology arises which appears to offer benefit not otherwise achievable, Medicare should undertake a prompt review using a mechanism similar to that developed by the Blue Cross Blue Shield organization (see Appendix E). The technology assessment program of Blue Cross Blue Shield, called TEC, establishes a methodology to develop appropriate patient selection criteria and medial center participation. In essence, it involves a process which has been designed to be a model of objective, science-based assessment of clinical effectiveness without regard to cost.

2. As part of the assessment process of new interventions and operations, I would suggest that HCFA request from editors of leading medical journals, copies of manuscripts which have been reviewed and accepted for publication on the subject in question. These could be reviewed by the HCFA TAC on a confidential basis in order to truly provide the most up-to-date information possible when making decisions which so critically affect the lives of Medicare beneficiaries. I have personally approached editors of several leading thoracic surgical and pulmonary medicine journals in the past week, and have obtained a list of publications on LVRS which are due for publication in the coming year. These are attached as Appendix F.

3. Promising procedures should be covered at specialized centers of excellence selected by Medicare, in exactly the same fashion as has recently been done by Medicare for coverage of lung transplantation.

4. Complete prospective accumulation of data should be a requirement of participation as a center of excellence, with periodic ongoing review by scientific advisory panel established by HCFA.

5. If and when a consistent pattern of benefit is established, the number of centers can be expanded or the procedure can be judged appropriate for unrestricted coverage by all Medicare providers. If the procedure fails to demonstrate sufficient benefit, a national policy of non-coverage can be instituted.

6. The type of liaison established between the National Institute of Health and HCFA, designed to evaluate the scientific aspects of LVRS should be encouraged. As a participant in the proposed LVRS trial, I am excited by the opportunity of studying in a rigorous, scientific fashion many of the unanswered questions regarding LVRS, including how does the operation work, can selection criteria be refined, what is the duration of benefit, what measurements of lung function correlate best with subjective improvement, what types of radiologic studies are most appropriate for selection of candidates, and many others. However, the answers to these questions should not be linked to coverage for Medicare beneficiaries. The information is not necessarily relevant to a Medicare coverage decision. If there is a group of patients for whom the value of the procedure is uncertain, then randomization of these patients between surgical and nonsurgical treatment would be scientifically valid and ethically defensible. The corollary, however, is true as well. If, for example, as is the case for LVRS, there is a well-defined patient population for whom the benefit is certain, randomization is not scientifically valid or ethically defensible.

I must reiterate that most non-Medicare beneficiaries currently have access to this procedure, whereas the process selected by HCFA to determine coverage has already denied coverage for the past 15 months, and will continue to deny or restrict coverage for many years to come. Some of the emphysema patients who have been denied access to LVRS must now be put back on the lung transplant waiting list, since they have no other option. This has the effect of reducing the number of lung transplants available to other patients, such as those with cystic fibrosis, for whom no other alternative exists.

The Health Care Finance Administration, should be given the necessary tools to solve this problem, including what the health technology committee of the Minnesota Health Commission refers to as "coverage with conditions," namely the ability to restrict coverage to selected centers during the developmental phase of new and potentially lifesaving surgical interventions.

Thanks to the pioneering work of many others, enormous support from colleagues and staff at the University of Toronto and Washington University in St. Louis, and a large measure of good luck, I have been privileged to spearhead the development of successful lung transplantation and to develop the lung volume reduction procedure for patients crippled by end-stage lung disease. I have made every attempt to develop both fields as rigorously, scientifically, and ethically as possible and to share as rapidly as possible our experience with colleagues around the world, so that as many patients as possible might benefit from these advances. In my opinion, I have spent far too much time battling, on behalf of my patients, for health care coverage. I wish I had been able to spend less time battling for acceptance and more time battling disease and providing service to my patients.

Thank you for this opportunity to testify on this urgent health care matter. I would be pleased to answer any questions you may have.

Appendix A

CHRONOLOGY OF GOVERNMENT ACTION REGARDING LUNG VOLUME REDUCTION SURGERY

11/15/96 The Agency for Health Care Policy and Research (AHCPR) publishes a Notice of Assessment of Medical Technology to determine the "safety and effectiveness" of lung volume reduction surgery (LVRS) in the Federal Register, calling for information on the risks, benefits, and costs associated with LVRS. The notice sets a data submission deadline of February 13, 1996.

12/195 HCFA announces its national coverage decision to the carriers not to cover LVRS beginning January 1, 1996.

3/27/96 HCFA's TAC meets and decides to continue its non-coverage decision.

4/24/96 HCFA and NIH announce their intention to collaborate on a multicenter, randomized clinical study of the effectiveness of LVRS (this predates the completion of the AHCPR assessment).

5/9/96 HCFA and NIH announce their joint sponsorship of a 7-year prospective randomized study to gather data on the safety and effectiveness of LVRS.

5/22/96 AHCPR issues its Health Technology Assessment entitled, "Lung Volume Reduction Surgery for End-Stage Chronic Obstructive Pulmonary Disease." The assessment lumps together all data for all variations of LVRS plus laser and concludes there is ambiguity and uncertainty in the data. AHCPR's recommendation does not discuss randomization to current medical treatment, capping the number of patients or centers involved in the study.

6/3/96 NIH issues its Request for Proposals from clinical centers to participate in the prospective randomized study, with an original deadline for submissions of August 5, 1996.

6/26/96 NIH amends it request for proposals, in response to concerns expressed by medical centers about the minimum of 50 surgeries required to qualify for consideration. It drops this requirement and extends the deadline for submissions to August 19,1996.

9/12/96 H.R. 3755 passes the Senate Appropriations Committee with additional language, requiring HCFA to analyze all of the data it has available to date and to report its recommendations regarding reimbursement for LVRS via a report to Congress by January 1, 1997.

9/28/96 Conference Report accompanying H.R. 2610 (of which H.R. 3755 became a part), accepts Senate bill language and states that the Congress is directing the Secretary of HHS to submit a report (to Congress by January 1, 1997) "describing the method and schedule for restoring Medicare coverage of lung volume reduction surgery." (emphasis added)

12/20/96 NIH announces selection of 17 centers (plus one coordinating center) to participate in 7-year prospective randomized study. The 30-member panel reviewing the applications consisted of 27 internists/pulmonologists and 3 surgeons. In fact, a few centers selected have very little surgical experience with the procedure which could adversely impact the outcomes HCFA and NIH are trying to measure. Other centers with significant surgical experience are not included.

1/1/97 Deadline for HCFA to submit report to Congress analyzing all available data and describing a schedule to restore Medicare coverage for LVRS.

1/23/97 HCFA writes to Senator Specter and asks for an extension of the January 1, 1997 deadline to "on or before April 1, 1997."

4/1/97 HCFA fails to submit report to Congress in timely fashion as required by law as well as within its own request for more time.

Appendix B

NIH–HCFA RFP Study Parameters for Lung Volume Reduction Surgery

- Prospective (therefore will not consider published or pre-publication peer reviewed data to date)
- Seven year study divided into three phases:

—Phase I: 9 months (December 20, 1996–September 19, 1997)
—*Principal investigators develop protocols to evaluate LVRS*
—Phase II: 5 years 3 months (September 20, 1997–December 19, 2003)
—*Conduct the study*
—Phase III: 12 months (December 20, 2003–December 20,2004)
—*Complete written report and manuscripts for publication*

- 12–15 medical centers plus one coordinating center to participate (17 selected plus one coordinating center—geographic distribution is skewed)
- Registry—recruit 13,000 emphysema patients (14% of approximately 91,200 potential candidates)
- Compare current medical treatment (CMT) to 2 types of LVRS: by median sternotomy and by video assisted thorascopic surgery (VATS)
- Randomization:

—Three armed trial:
—*I: CMT v. median sternotomy*
—*II: CMT v. VATS*
—*III: CMT v. median sternotomy v. VATS*
—Total of 2,580 patients selected from 13,000 patient registry (3% of approximately 91,200 potential candidates)
—*I: 495/495*
—*II: 495/495*
—*III: 200/200/200*
—*Therefore, 1,390 patients receive LVRS (2% of approximately 91,200 potential candidates) and 1,190 receive current medical treatment*

- REP is silent on the issues of having more than 2,580 patients enter the study, or ending the study before december 20,2004

Appendix C

Minnesota HTAC Report

Lung Volume Reduction Surgery for Diffuse Emphysema

HTAC, Health Technology Advisory Committee, Minnesota Health Care Commission, Report, February 1997, Lung Volume Reduction Surgery for Diffuse Emphysema, The mission of the Health Technology Advisory Committee is to provide objective, scientifically based information on health technologies to the Minnesota Health Care Commission. For additional information, please contact us at: 121 East 7th Place, Suite 450, P.O. Box 64975, St. Paul, MN 55164–0975, (612) 282–6374

Lung Volume Reduction Surgery for Diffuse Emphysema, Final Report

Produced by the Health Technology Advisory Committee and Approved by the Minnesota Health Care Commission, February 19, 1997

Health Technology Advisory Committee

**John Abenstein, MSEE, M.D.
F. Blanton Bessinger, M.D.
Catherine Borbas, Ph.D.
Dianne Brundage, Pharm.D.
Diane Davies, M.D.
Joanne M. Disch, Ph.D., R.N.
Darryl T. Gray, M.D., Sc.D.
* Susan J. Isernhagen, P.T.

Ms. Nancy Johnson
Mr. David Jones
Mr. Paul Kralovec
Caroline McKay, M.D.
Mr. Dennis Miley
Trudy Ohnsorg, M.P.H.
Delwin K. Ohrt, M.D.
Reinhard Priester, J.D.
Andra Thomas, R.N.
Catherine Wisner, Ph.D.

*Chair
**Vice-Chair

Lung Volume Reduction Surgery (LVRS) Work Group

F. Blanton Bessinger
Joanne Disch
Darryl Gray
Reinhard Priester
Andra Thomas

Consultant

Dashe & Thomson

Background and Purpose of the Health Technology Advisory Committee (HTAC)

This health technology assessment report was produced by the Health Technology Advisory Committee (HTAC) of the Minnesota Health Care Commission (MHCC). The HTAC was established in 1992 by the Minnesota State Legislature as a nonpartisan, independent body charged with assessing new and existing health care technologies and applying a Minnesota perspective. It bases its evaluations on existing research and assessments of technology, providing balanced, objective information important to the entire health care system. The HTAC conducts its assessments in an open, public forum, actively soliciting comment from the public and stakeholder groups.

Health technologies are broadly defined in statute to include "...drugs, devices, procedures, or processes applied to human health care... ." Technologies are selected for review by the volunteers who make up the HTAC, who represent diverse sectors of the health care industry.

The criteria for selection of health care technologies for evaluation include: the level of controversy within the medical or scientific community, including questionable or undetermined efficacy; cost implications; potential for rapid diffusion; impact on a substantive patient population; existence of alternate technologies; impact on patient safety and health outcome; public health importance; level of public and professional demand; social, ethical and legal concerns; and, the prevalence of the disease or condition.

Once selected, technologies are evaluated on issues of safety, clinical effectiveness, improvement in health outcome and cost effectiveness. With the help of outside consultants, relevant data, studies and other information is critically reviewed and analyzed by the HTAC work groups. A technology assessment report is prepared and submitted to the HTAC for discussion and approval.

Two formal opportunities for public input occur. A 30-day public comment period follows HTAC's approval of the report. Letters received during this time are incorporated into the final report which is then submitted to the MHCC for their review and approval. Public testimony is heard by the MHCC and is taken into consideration. The public is also welcome to attend work group meetings and often plays an active role in the development of an HTAC report.

Upon the MHCC's approval, the report is made available through the Minnesota Health Information Clearinghouse.

Lung Volume Reduction Surgery (LVRS) for Diffuse Emphysema

A notice soliciting public comment appeared in the January 21, 1997 Minnesota State Register. No public comment on the report was received. Following the public comment period, the report was reviewed and approved by the Minnesota Health Care Commission at their February 19, 1997 meeting. No public testimony was offered at that time.

The information contained in this report has been judged to be current as of Fall 1996. Readers should be aware that new information or developments may require additional assessment or interpretation of previous findings. Readers should also be aware that the studies and information used by HTAC in completing its assessments are typically designed to answer questions relating to classes of patients, rather than to a specific individual. Individuals making personal health care decisions are encouraged to obtain additional information in consultation with their physician.

For additional information about the Health Technology Advisory Committee (HTAC) contact: Minnesota Health Care Commission, P.O. Box 64975, 121 E. Seventh Place, Suite 450, St. Paul, Minnesota 55164–0975, (612) 282–6374

Distribution Plan

Notices announcing publication of Lung Volume Reduction Surgery for Diffuse Emphysema, by the Health Technology Advisory Committee and the Minnesota Health Care Commission will be sent to individuals and organizations on the report distribution master list. In addition, the report will be sent to the following organizations and specialty societies: American Association of Cardiovascular and Pulmonary Rehabilitation, American Association for Thoracic Surgery, American College of Chest Physicians, the American College of Surgeons, and the American Thoracic Society. The report will also be sent to both the national office and the Minnesota chapter of the American Lung Association.

Lung Volume Reduction Surgery for Diffuse Emphysema, Final Report

This report examines lung volume reduction surgery as a treatment for diffuse emphysema. The Health Technology Advisory Committee (HTAC) studied this procedure because of the increased frequency of emphysema and because emphysema has significant health and cost implications. This report is intended to help patients, their families, health care providers, payers, and Minnesota policy-makers make informed choices and decisions.

Background

Emphysema

Over 1.9 million Americans have emphysema, an incurable degenerative lung disease. Although emphysema may have genetic origins or arise from poor air quality in industrial settings, the main cause of the disease is chronic tobacco smoking. As the disease progresses and lung tissue continues to degrade, more and more air is trapped within the lungs. The lungs become so enlarged that inhaling more air becomes difficult and trapped air must be forcibly exhaled. The result is hyperinflated lungs, a distended chest cavity, breathlessness (dyspnea), oxygen starvation and restriction of normal daily activities. Life expectancy for late-stage emphysema patients is 2 to 5 years.

The prevalence of emphysema has increased more than 40% in the last decade. Approximately 34,000 Minnesotans have emphysema; of these, 15–20% are in the late-stage of the disease requiring aggressive medical management such as long-term oxygen therapy (LTOT), medication, smoking cessation programs, and pulmonary rehabilitation programs. At this time, standard therapy for extending life in late-stage emphysema patients is smoking cessation and LTOT.

Diffuse Emphysema versus Bullous Emphysema

Generally, emphysema is not distributed homogeneously throughout the lungs. Some portions of the lung are more affected by the disease than others and will ventilate more slowly than the healthier regions. Severely damaged lung tissue may exhibit areas of large air-filled sacs called bullae; this condition is called bullous emphysema and is not the subject of this report. Diffuse emphysema, then, is defined as a condition in which some lung tissue is virtually nonfunctional, but has no large bullae, while other portions of the lung are less diseased and functioning in a more normal manner. High resolution computed tomography (CT scan) is used to assess the condition of emphysematous lung tissue.

Lung Volume Reduction Surgery (LVRS) for Diffuse Emphysema

This report examines the current status of lung volume reduction surgery to treat diffuse emphysema (LVRS). Many pulmonologists and thoracic surgeons believe that the surgery has the potential to relieve the symptoms of late-stage diffuse emphysema for a select group of patients. The procedure is not curative in any way and can best be described as returning the disease of an individual patient to an earlier stage. Due to the emerging status of the application, neither long term clinical effectiveness nor cost effectiveness have been evaluated.

LVRS was originally proposed by Otto Brantigan, M.D. more than 35 years ago. He theorized that surgical excision (cutting away) of diseased lung tissue would reduce lung volumes, thereby restoring the outward elastic pull on the small airways and reducing airway obstruction. Brantigan performed lung reduction for diffuse emphysema in 33 patients with an initial mortality rate of 18%. The high mortality rate discouraged further use of this application for diffuse emphysema for some time.

In the 1990s, the increasing prevalence of emphysema, and recent advances in pulmonary rehabilitation, anesthetic technique and surgical instrumentation generated a resurgence of interest in LVRS as an alternative to medical management, or as a bridge, or in addition to, lung transplantation. Many clinical centers have been publishing data indicating that a lung reduction of 20 to 30% in patients with diffuse emphysema allows the chest wall and diaphragm to resume a more normal position, thus improving the mechanics of breathing. Mortality rates vary, but are much lower than originally reported.

Recent published studies[1] of patients who have undergone LVRS for diffuse emphysema demonstrate short-term (6 to 18 months) improvements in pulmonary function [measured by FEV–1, VC, TLC, RV[2]] and improved dyspnea assessments. Quality of life[3] improves dramatically in some cases; many patients are no longer dependant on oxygen and resume daily activities.

However, the published data should be interpreted with caution. There is little consensus among medical centers on choosing which patients are most likely to be helped and not harmed by the procedure (see Appendix II). Patient samples have been small and studies have not been randomized, which is the gold standard to determine effectiveness. Also, a variety of surgical techniques are being used for lung reduction for diffuse emphysema; no standard surgical protocol has been developed. Further, because of the emerging status of this procedure, there is no information on long-term outcome (2 to 5 years).

National Institute of Health—Clinical Trial for LVRS

The National Institute of Health (NIH) announced on June 10, 1996 that it will sponsor a seven-year clinical trial.[4] The trial is expected to answer these questions:

- Which patients will benefit from LVRS?
- What is the best surgical procedure?
- What are the long-term outcomes of the surgery?

The trial will involve approximately 2,500 patients at 10 to 15 centers[5] throughout the United States. The centers involved are in endnote 5.

The Health Care Financing Administration (HCFA) will reimburse centers for Medicare-eligible patients involved in the NIH clinical trial; it is not known whether private payers will participate with funding for those patients who are not covered by Medicare.

Findings

Provider Charges: Medical Management and LVRS

To date, over 70 LVR surgeries have been performed at medical centers in Minnesota. However, cost effectiveness, including post-surgical use of health care services, for LVRS versus continued medical management, has not been evaluated.

Medical management, for patients who do not undergo LVRS, includes long term oxygen therapy (LTOT), medication, and hospital and emergency room visits. According to the Institute for Clinical Systems Integration, total Medicare payments spread over 5 years (maximum life expectancy), not including rehabilitation, are estimated at $65,800 per patient. This includes $3,360/year for LTOT and $10,000/year for hospital charges. An eight week pulmonary rehabilitation program ranges from $ 1,500 to $5,000. However, a center in Minnesota reports that medical management charges of $70,000/year per patient are not uncommon.

Charges for LVRS vary among centers. The estimated cost for LVRS at one center in Minnesota ranges from $30,000 to $55,000, excluding physician fees. This includes hospital costs, of a 14–18 day hospital stay, with 4–5 days in the intensive care unit.

At another Minnesota center the range of total hospital charges, excluding physician fees, ranges from $29,000 to $39,000. No information is available for post-surgical patient utilization of services or charges.

Reimbursement Issues

Minnesota health plans vary in their classification and coverage of the surgery. Blue Cross/Blue Shield of Minnesota's medical policy states that LVRS is an "investigative procedure" and covers the surgery only when performed at Mayo Clinic, Rochester, and the University of Minnesota Hospitals in Minneapolis. Medica's medical policy states that "lung volume reduction is experimental" and offers no coverage for the surgery.

The Health Care Financing Administration (HCFA—which makes decisions regarding Medicare reimbursements) halted Medicare payments for LVRS in December 1995 pending a health technology assessment by the Agency for Health Care Policy and Research (AHCPR). On the basis of the AHCPR assessment, completed in April 1996, HCFA has determined that it will pay only for those patients undergoing lung reduction for diffuse emphysema in the context of the NIH clinical trial which will commence in 1997 (see clinical trial described above and in endnote 4).

Conclusions from the Data

After review of the available literature and consultation with experts in this field, HTAC has determined that:

- Short term effectiveness of 6 to 18 months has been demonstrated.
- The benefits of the surgery appear to outweigh the harm.
- Mortality rates are at an acceptable level for a major pulmonary/thoracic procedure.
- It appears that, on a short-term basis, health care costs for a patient after LVRS are less than for the patient before LVRS. For example, patients may not need LTOT.

These conclusions led HTAC to the following recommendations.

Recommendations

The published information and testimony of experts reviewed by HTAC suggests that LVRS may benefit a select group of Minnesota patients. However, many questions remain unanswered:

1) How should patients be selected for LVRS?
2) What is the optimal surgical technique for LVRS?
3) What is the long-term outcome of LVRS?
4) What is the cost effectiveness of LVRS compared to medical management with LTOT?

Recommendation I. Coverage with Conditions

HTAC recommends that coverage for LVRS for diffuse emphysema include conditions. "Coverage with conditions" means that the payer will provide insurance payment, but only if certain conditions are met. The conditions attached to coverage should be specifically designed to aid the data collection and analysis needed for more definite conclusions regarding the long-term safety, effectiveness and cost of LVRS for diffuse emphysema.

For example, coverage could be conditioned on participation of the patient and center in either the NIH trial or (for patients not eligible to enter the NIH trial) in prospective outcomes data collection, coordinated with national efforts and between all centers in Minnesota performing LVRS.

Recommendation II. Requirements of Facility and Its Staff for Coverage with Conditions

LVRS should only be performed at medical centers which offer a complete LVRS program:

1. The institution must have board certified or eligible pulmonologists, thoracic surgeons, and anesthesiologists familiar with complex problems in general thoracic surgery.
2. Nurses, respiratory therapists, pain management services and a suitably equipped and staffed intensive care unit should be available.
3. The program must also offer pre- and post-operative rehabilitation.
4. The surgery should not be restricted to academic medical centers.
5. Patient selection criteria must be well-defined (See appendix II).
6. The center must participate in a clinical registry and provide data for collection.

Recommendation III. Requirement of Participation in Clinical Trial/Registry for Coverage with Conditions

1. Centers in Minnesota which are not accepted for the NIH clinical trial must follow guidelines for patient selection outlined in the NIH request for proposal, and collect the data needed to answer the four questions above.
2. Randomized trials are encouraged, depending on the questions that need to be answered and if trials are feasible to conduct. A mandatory registry[6] approach to data collection is suggested where randomized trials cannot be performed.

Appendix I: Guidelines From Other Sources

American Lung Association

"At this point in time, the operation should not be considered experimental, although insufficient data are available to determine if lung volume reduction surgery should be considered standard therapy. Since there are many questions to be answered we recommend that this operation be performed only at centers where these procedures can be more completely studied through clinical trials and extensive physiologic evaluations."

ICSI Committee Summary

The ICSI Technology Assessment Committee finds that the results to-date of lung reduction surgery for emphysema show a definite improvement in lung function, exercise tolerance and psychosocial status among undifferentiated and poorly defined groups of patients.

However, to better define appropriate indications and long-term results, patients requiring lung reduction surgery should be enrolled in carefully designed scientifically valid clinical trials conducted at institutions with the necessary expertise. Accordingly, long-term data are critical before assessment of safety and efficacy of reduction pneumoplasty is possible.

American College of Chest Physicians—Response to HCFA

1) Patients who are being considered for LVRS should be evaluated by a pulmonologist and a thoracic surgeon who are knowledgeable and experienced in caring for patients with severe emphysema. Evaluation should include:

a. CT scan of chest
b. Full pulmonary function tests
c. Quantitative ventilation/perfusion lung scan
d. Evaluation of cardiac function
e. Objective test of exercise performance

Usually, only 10–20% of patients evaluated are considered to be candidates for LVRS. Cigarette smoking in the past six months is an absolute contraindication. Patients with other life-threatening illnesses are unlikely to be appropriate candidates.

2) Intensive medical therapy, including pulmonary rehabilitation, is the mainstay of treatment of diffuse emphysema. If sufficient improvement in symptoms does not occur following intensive medical treatment, surgical options including LVRS or lung transplantation may be considered

3) Any institution carrying out LVRS should have board certified or eligible pulmonologists thoracic surgeons, and anesthesiologists familiar with complex problems in general thoracic surgery. Nurses, respiratory therapists, a pain management service and a suitably equipped and staffed intensive care unit should also be available.

4) Careful records must be kept, continually updated and shared through a national data bank. As specific information becomes available and criteria established for selection and care of these patients, this information should be disseminated as efficiently as possible.

Appendix II: Sample Patient Selection Criteria from Several Centers

Criterion	Center A	Center B	Center C	Reason
Smoker?	no	no	no	Reduces chances of post op smoking; indicates patient's commitment to recovery
FEV–1 of predicted [1].	20–30%	less than 35%	15–35%	There is a FEV–1 "window" of patients suited for LVRS who are neither too ill nor too healthy.
PCO2 [2]	less than 55 mm.	(relative)	less than 50 mm.	Too much CO2—air exchange is poor; post op may require ventilator
Steriods	no	NA	NA	Use of steriods may slow healing process after surgery
Pre operative Rehabilitation.	yes	yes	yes	Increases strength, stamina, endurance motivation; improves post op healing.
Age	less than 75 years.	less than 75 years.	less than 75 years.	Post op complications (such as pneumonia and blood clots) may arise in older patients whose endurance and stamina is weak.

[1] FEV–1 Forced Expiratory Volume 1—the amount of air exhaled in the first second of forced expiration.

[2] PCO2 Partial pressure of CO2 measures whether there is too much CO2 and not enough O2 (oxygen) in the bloodstream

Appendix III: Methods and Sources

Methods

This report is the result of a collaborative effort involving the Minnesota Health Care Commission (MHCC), the Minnesota Department of Health's Division of Health Policy and Systems Compliance, the Health Technology Advisory Committee work group members and staff, field experts, and an independent technical writer/consultant. Current sources (see below) were thoroughly analyzed, synthesized and summarized before inclusion in this report. The text and data included in the report were reviewed and revised several times to insure objective, accurate and understandable information

This report may be used by physicians, health care providers, insurers, legislators, and health care recipients in making informed decisions and choices regarding lung volume reduction surgery for diffuse emphysema.

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Endnotes

1. See Sources: Cooper et al., 1995, Gaisert et al., 1996, McKenna et al. 1996, Sciurba et al., 1996, and Zenati et al., 1995.

2. Standard Pulmonary Function Tests measure how well the lungs are working:

FEV–1 Forced Expiratory Volume 1—the amount of air exhaled in the first second of forced expiration.

VC: Vital Capacity is the total amount of air which can be slowly and completely expired.

TLC: Total Lung Capacity is the total volume of air in the lungs at full inspiration.

RV: Residual Volume is the air in the lungs after full expiration.

3. Quality of Life—Subjective assessments based on patient's rating of pain, energy, emotional reaction, physical mobility, etc., related to his or her daily activities.

4. The NIH Request for Proposals, which outlines the design of the study, is available at gopher://gopher.nih.gov/00/res/nih-guide, quoted in part below:

"The National Heart, Lung, and Blood institute (NHLBI) of the National institutes of Health (NIH) and the Health Care Financing Administration (HCFA) will jointly sponsor and support a seven year multi-center randomized, clinical trial in association with a prospective registry to examine the role of Lung Volume Reduction Surgery (LVRS) in the treatment of end-stage emphysema, evaluate the long term outcome of LVRS on function, morbidity and mortality and define appropriate patient selection criteria for the procedure. The program will consist of approximately 10 to 15 clinical centers and a coordinating center...

Clinical centers must document a strongly integrated team with expertise in the following areas: thoracic surgery, the surgery being offered, the pre-, peri- and post-operative care of end-

stage emphysema patients undergoing thoracic surgery, pulmonary medicine and the care of end-stage emphysema patients, the rehabilitation and education of end-stage emphysema patients, the conducting of clinical trials, pulmonary physiology, cardiology, radiology and evaluation of dyspnea and quality of life. in addition, the centers must document strong collaborative ties with other consultative services.

The study will be conducted in three phases. Phase I (9 Months) will be for development of a protocol and manual of operations and recruitment and training of personnel. Phase 11(63 Months) will be for recruitment of patients, treatment and follow-up. Phase III (12 Months) will be for analysis of data and writing of manuscripts describing results of the study.

A registry will be established to serve as a repository of severe end stage emphysematous patients, who have been referred for evaluation for LVRS, transplant or pulmonary rehabilitation to any of the participating clinical centers. Baseline clinical data will be invited for inclusion in the randomized study. Patients, who are not randomized, but agree to be in the registry will be followed twice yearly. The registry will provide (1) information on patients referred for end-stage emphysema, (2) data on the outcome of these patients; (3) a source of patients for randomization, and (4) allow comparison of patients who are randomized to the larger pool of patients with end stage emphysema. Patients meeting eligibility requirements will be randomized to receive either maximal medical therapy or maximal medical therapy with LVRS.

LVRS will be performed by median sternotomy or by bilateral video-assisted thorascopic surgery (VATS) with excision of 20 to 30 percent of each lung. Centers will apply to randomize to either (a) medical therapy versus medical therapy with LVRS by median sternotomy, (b) medical therapy versus medical therapy with LVRS. by bilateral VATS or (c) medical therapy versus medical therapy with LVRS by median sternotomy versus medical therapy with LYRS by bilateral VATS. Maximum medical therapy will include pulmonary rehabilitation and education. End-points will include exercise ability, pulmonary function, quality of life, morbidity and mortality. The study population will consist of 200 patients recruited into each arm of the three arm trial comparing surgery A versus surgery B versus medical therapy. An additional 495 patients will be recruited into each of two arms among clinical centers performing only one kind of surgery and medical treatment.

This will require a total of 2580 participants in the three armed and two arm trials combined. The HCFA will pay all allowable clinical costs for its beneficiaries."

5. NHLBI Lung Volume Reduction Surgery Study Clinical Centers from http://www.nhlbi..nih.gov/nhlbi/lung/lvrsctr.htm downloaded on January 6, 1997

Baylor College of Medicine, Houston, TX, Principal Investigator: Rafael Espada, MD, 713–798–4556, Patient Referral: Charles Miller, 1–800–622–9567

Brigham & Women's Hospital, Boston, MA, Principal Investigator: John J. Reilly, MD, 617–732–7420, Patient Referral: Tammy Weihrauch, 1–888–BWH–LUNG (1–888–294–5864)

Cedars-Sinai Medical Center, Los Angeles, CA, Principal Investigator: Robert McKenna, MD, 213–977–1170, Patient Information: Brenda Williams, 1–800–CEDARS–1 or Fax 310–854–3917, Other Information: Zab Mohsenifar, MD, Principal Investigator, 310–855–4685 or Fax 310–967–0129

Cleveland Clinic Foundation, Cleveland, OH, Principal Investigator: Janet R. Maurer, MD, 216–444–6505, Patient Referral: 1–800–822–9488, Other Information: Barbara Higgins, RN, 1–800–223–2273, Ext. 54215 or 216–445–4215

Columbia University, New York, NY, Principal Investigator: Mark Ginsburg, MD, 212–305–3408, Patient Referral: Patricia A. Jellen, MSN, RNC, 212–305–1158

Duke University Medical Center, Durham, NC, Principal Investigator: Neil R. MacIntyre, MD, 919–681–2720, Patient Referral: Janet Johns, 919–681–2720

Mayo Clinic, Rochester, MN, Principal Investigator: Rolf D. Hubmayr, MD, 507–255–5441, Patient Referral: Kristin A. Bradt, 507–284–4619

National Jewish Center for Immunology and Respiratory Medicine, Denver, CO, Principal Investigator: Reuben M. Cherniack, MD, 303–398–1503, Patient Referral: Lung Line, 1–800–222–LUNG, Other Information: Physician Referral Line, 1–800–NJC–9555

Ohio State University, Columbus, OH, Principal Investigator: Philip T. Diaz, MD, 614–293–4925, Patient Referral: Mary Lou Coffee, 614–293–4509

Saint Louis University, St. Louis, MO, Principal Investigator: Keith'S Naunheim, MD, 314–577–8360, Patient Referral: Gina Roelke, 800–268–5880, Other Information: Laura Taylor Bianchi, 314–577–8360

Temple University, Philadelphia, PA, Principal Investigator: Gerard J. Criner, MD, 215–707–8113, Patient Referral: Anne Marie Kuzma, RN, 215–707–1334

University of California, San Diego Medical Center, San Diego, CA, Principal Investigator: Andrew Ries, MD, 619–294–6068, Patient Referral: Trina Limberg, 619–294–6066

University of Maryland at Baltimore, Baltimore, MD, Principal Investigator: Mark J. Krasna, MD, 410–328–6366, Patient Referral: Karen King, RN, 410–328–2168

University of Michigan, Ann Arbor, MI, Principal Investigator: Fernando J. Martinez, MD, 313–936–5201, Patient Referral: Telecare, 800–742–2300 Routing #6235, Other Information: Pamela Lewis, RN, 313–647–7840

University of Pennsylvania Medical Center, Philadelphia, PA, Principal Investigator: Larry Kaiser, MD, 215–662–7538, Patient Referral: Penn Health Customer Service, 1–800–789–PENN

University of Pittsburgh, Pittsburgh, PA, Principal Investigator: Robert J. Keenan, MD, 412–648–8474, Patient Referral: Betsy George, RN, 412–648–6736

University of Washington, Seattle, WA, Principal Investigator: Richard K. Albert, MD, 206–543–3166, Patient Referral: Doctors, Inc., 1–800–826–1121

Washington University, St. Louis, MO, Principal Investigator: Joel D. Cooper, MD, 314–362–6021, Patient Referral: Deen Scharff, 314–362–6044

Coordinating Center, The Johns Hopkins University, Baltimore, MD, Principal Investigator: Steven Piantadosi, MD, 410–955–4884

6. The LVRS data registry previously located in St. Louis, MO, is in the process of relocating to Minnesota at the time of writing.

Appendix D

BCBS Technologies Assessment

The Blue Cross and Blue Shield Association assesses the effectiveness of new technologies and treatments by evaluating scientific evidence. The Blue Cross and Blue Shield Association (BCBSA) established a technology assessment program in 1984, called TEC, to assist our member Plans in evaluating new technology. The BCBSA TEC program has been a pioneer in the use of scientific evidence to form conclusions about the effectiveness of new technologies. It is one of the nation's leading technology evaluation efforts and has conducted more than 250 assessments since its creation.

The TEC program was expanded in 1993 with the collaboration of Kaiser-Permanente and now serves as a resource to 14 health plans outside the Blue Cross and Blue Shield System in addition to Kaiser-Permanente.

The Medical Advisory Panel, which is the program's external review body, is comprised of recognized experts in scientific methods, clinical research, medical practice, and medical ethics. A majority of the Panel's members are independent medical experts having no affiliation with third party payers. Members of the Medical Advisory Panel include appointees from the American College of Physicians, the American Academy of Family Physicians, and the American Academy of Pediatrics.

The TEC Program uses five objective scientific criteria in determining whether the technology in question improves net health outcomes such as length of life, ability to function, or quality of life. Cost is not a consideration in TEC assessments. The five TEC criteria are:

1. The technology must have final approval from the appropriate government regulatory bodies.
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.
3. The technology must improve the net health outcome.
4. The technology must be as beneficial as any established alternatives.
5. The improvement must be attainable outside the investigational settings.

Professional staff of the TEC Program who are M.D.s and Ph.D.s evaluate the scientific evidence on a technology and prepare a written assessment addressing the five criteria. The evidence is culled from published peer-reviewed literature, abstracts presented at major professional meetings, and from scientific forums periodically convened by TEC that enable researchers to present their most current findings on important new technologies. The assessments are reviewed by our expert Medical Advisory Panel which approves, revises, or reverses the staff's recommendations.

The assessments developed by TEC are scientific opinions designed to provide information to those who deliver and manage medical care. The TEC process has been designed to be a model of objective, science-based assessment of clinical effectiveness without regard to cost.

Use of TEC assessments by Blue Cross and Blue Shield Plans and other payers is voluntary. They are one of many resources used in the formulation of coverage policy.

Appendix E

Partial List of Lung Volume Reduction Articles Published

1. Eugene J, DaJee A, Kayaleh R, Gogia H, Santos C, Gazzaniga A. "Reduction Pneumonoplasty For Patients With a Forced Expiratory Volume in 1 Second of 500 Milliliters or Less." Annals of Thoracic Surgery, 1997;63:186–92.
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Appendix F

Partial List of Lung Volume Reduction Articles in Press

1. Slone R, Pilgram T, Gierada D, Sagel S, Glazer H, Yusen R, Cooper J. "Comparison of Preoperative Radiologic Features and Clinical Outcome Following Lung Volume Reduction Surgery." Radiology (In press)
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4. Bagley P. "Lung Volume Reduction Surgery at a Community Hospital: Program Development and Outcomes." Chest (In Press).
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Mr. MCCRERY. Thank you, Dr. Cooper, and I thank all of the witnesses for appearing today and sharing with us your information and your views.

Dr. Cooper, obviously, this is an area where there is some agreement, at least with HCFA, and all I can tell you is that the Members of this Subcommittee will be happy to work with you and try to bring as much information as possible to HCFA.

But for now, thank you, gentlemen, very much. We look forward to continuing to work with you as we try to promote the best and most efficient Medicare Program.

The Subcommittee is adjourned.

[Whereupon, at 3 p.m., the hearing was adjourned.]

[Submissions for the record follow:]

Statement of American Lung Association and American Thoracic Society

These comments are submitted on behalf of the American Lung Association and its medical section, the American Thoracic Society.

Founded in 1904 to fight tuberculosis, the American Lung Association (ALA) is the oldest nationwide voluntary health agency in the United States. Along with its medical section, the American Thoracic Society (ATS)—a 12,500 member professional organization of physicians, scientists, and other health professionals specializing in pulmonary and critical care medicine and lung research—the American Lung Association provides programs of education, community services, advocacy and research to fight lung disease and promote lung health.

The ALA/ATS would like to take this opportunity to bring to the attention of the Committee its opinion on the matter of medical innovation and technology, and specifically how a new medical innovation, Lung Volume Reduction Surgery (LVRS), is relevant to the larger discussion of HCFA's reimbursement decision-making process.

LUNG DISEASE IN THE MEDICARE POPULATION

Lung disease is the third leading cause of death in the U.S., responsible for one in every seven deaths. More than 30 million Americans suffer from a chronic lung disease, costing the U.S. an estimated $84.4 billion annually. The prevalence of chronic lung disease varies with age, but for most age categories chronic lung disease hits individuals 65 years and older the hardest. The prevalence of emphysema, the fourth leading cause of mortality, increases substantially with age, affecting 15.6 people per 1,000 in the 45–64 year range and nearly doubling to 29.8 per 1,000 after age 65. Current data estimate 13.5 million Americans are afflicted with emphysema.

LUNG VOLUME REDUCTION SURGERY (LVRS)

Lung volume reduction surgery encompasses a variety of surgical procedures that may alleviate the symptoms of advanced chronic obstructive lung disease due to emphysema. Currently, there are a number of surgical techniques for the treatment of emphysema, namely, the excision of large bullae by thoracotomy, or thoracostomy and the resection of diffusely emphysematous lung tissue. The latter is generally referred to as lung reduction surgery.

Based on results reported in peer review journals, abstracts, and presentations, the surgery has been proven to be effective in some, but not all patients with COPD. A great deal of media coverage about the potential benefits to LVRS has created a stir of excitement and hope for the many patients inflicted with the disease. However, the reports in peer review medical literature are limited, making the demand for guidance regarding the safety and efficacy of the procedure and patient selection criteria even greater.

In September 1995, the National Heart, Lung and Blood Institute held a meeting attended by experts in thoracic surgery and pulmonary medicine among others, to discuss the recent trends and concerns surrounding LVRS. At that meeting, it was

decided that LVRS was a promising new medical innovation, but that data supporting its effectiveness had not been well documented. At the point of the meeting, LVRS was covered as a surgical procedure under Medicare.

Current Challenges

Policy makers continue to face difficult challenges in an era where budget constraints necessitate difficult choices. These challenges are even greater when decisions directly and substantially affect the health of our nation. The ALA/ATS believes that medical research is a critical investment to the future of all Americans. Promising new technologies and in the case of emphysema, surgical procedures, have begun to proliferate the marketplace. While such advances provide hope for patients inflicted with chronic diseases, the medical community has the responsibility to ensure the safety and efficacy of new treatments. And, in light of budget constraints, medical professionals must also be prepared to justify the effectiveness of surgery given the financial implications.

Economic Implications

In a cost-conscious environment, substantiated claims must be well documented for a new procedure to be considered for reimbursement. In January of 1996, the Health Care Financing Administration (HCFA) retracted its Medicare coverage policy for LVRS due to concerns voiced by the medical community and unsubstantiated claims as to the benefits of this new medical advancement over existing treatment and therapy. To place this concern in context, charges for lung reduction surgery without any complications using a median sternotomy approach and a short hospital stay of seven days at a major teaching hospital have been documented to total between $35,000–$45,000. One of the most common complications with any resectional lung surgery is persistent air leak. Persistent air leak in turn leads to longer hospital stays and in one documented study, air leaks lasted more than seven days in 55% of patients. Longer hospital stays stemming from complications can result in total expenditures of over $60,000 per surgical procedure.

Further, any major thoracic procedure is likely to carry risks of high mortality. Mortality rates as high as 12.5 percent have been reported in the perioperative period during surgery for emphysema, and an additional 10 percent mortality may be seen in the five months following major surgery. And, prolonged hospitalization is highly correlated with increased morbidity.

Recommendations

There is little dispute that medical research has shed light on new, state-of-the art technology that has resulted in longer life and often, improved quality of life for individuals. At the ALA/ATS International Conference in May 1996, the ATS prepared a position paper in support of our recommendation for continued research to substantiate LVRS as a viable treatment option. The position paper is attached and is submitted for the record as well. Our position for a thoughtful, sound approach to continued research into the risks and benefits of LVRS remains. The ALA/ATS believes that medical innovation resulting from valid research can lead to positive outcomes. Medicare beneficiaries deserve a health care system that encourages medical innovation while ensuring the safety for all patients.

ALA/ATS supports HCFA's cooperative effort with the NHLBI to conduct a clinical trial assessing the benefits and risks associated with LVRS. Through this trial, important guidelines can be established to assist patients and medical professionals weigh the benefits and consequences of the surgical treatment. It is the hope of ALA/ATS that medical research into new innovative and advanced procedures will continue to provide options where current treatments do not exist and provide new procedures for those that have become arcane so that our citizens may continue to benefit from safe and efficacious procedures.

Lung Reduction Surgery

ATS Position Paper

What is lung volume reduction surgery?

Lung volume reduction surgery is a general term encompassing a variety of surgical procedures that are offered to alleviate the symptoms of advanced chronic obstructive lung disease due to emphysema. Currently the operations used to treat emphysema include the excision of large bullae by thoracotomy or thoracostomy and the resection of diffusely emphysematous lung tissue. This latter surgery, variably referred to as lung reduction surgery, pneumectomy, and reduction pneumoplasty can be accomplished through a variety of incisions (sternotomy, clam shell, thoracotomy) or by thoracoscopy using a staple procedure or laser applications. Currently the choice of techniques depends on the surgical expertise and preference of the operator.

The first series of patients who were treated with pulmonary resection for emphysema was reported by Brantigan and Mueller in the late 1950's (1). It was postulated that multiple wedge excisions of emphysematous lung tissue would reduce lung volume and thereby improve outward elastic recoil and airway patency of the intrathoracic airways. The authors also believed that lung volume reduction would result in a less expanded thoracic cage and diaphragm and that this would improve the mechanical function of the muscles of respiration. Also, by removing localized emphysematous areas, lung expansion of previously compressed more normal lung tissue would occur. While Brantigan and Mueller's surgical intervention in the 1950's resulted in clinical benefit to most of the patients studied, a prohibitively high rate of postoperative morbidity and mortality resulted in limited acceptance of this procedure. Recently there has been a resurgence of interest in volume reduction surgery for emphysema. Taking advantage of advances in anesthesia and postoperative care over the past three decades, as well as lessons learned from the management of patients undergoing lung transplantation, Cooper et al (2) has reintroduced bilateral surgical lung resection for severe emphysema. In addition, several centers have reported their results with unilateral and bilateral volume reduction surgery by thoracoscopy using laser technology or by stapled lung reduction techniques (3–7). At the present time, the number of operations being performed in this country is increasing in an uncontrolled fashion and may number in the thousands. There has been extensive lay and medical media coverage at the local and national level, though reports in the peer reviewed medical literature at the present time are limited. This has generated extraordinary physician and patient demand for information on the procedure and specific advice regarding the efficacy, safety, patient selection, and choice of a surgeon or hospital for such surgery.

What is the efficacy of the surgery?

Based on results reported in peer review journals, abstracts and presentations at national meetings, the procedure appears efficacious for some, but not all patients with advanced COPD due to emphysema. Unfortunately, limited follow up experience to date does not provide adequate patient selection criteria. Several centers have documented postoperative improvement in exertional dyspnea, measurements of pulmonary function, exercise capacity and objectively scored quality of life indices. Improvements in exercise capacity have been reported preoperatively in patients undergoing a comprehensive program of pulmonary rehabilitation in preparation for surgery. The first published paper (2) on simultaneous bilateral pneumectomy suggested that postoperative patients continue to improve up to six months. A follow up series from the same institution (8) showed that the improvement can be sustained for up to 12 months. Patients have been evaluated post-bilateral pneumectomy beyond one year, but most operations appear to have been done in an uncontrolled fashion. A small number of published reports are available regarding thoracoscopic lung reduction surgery for emphysema (3–7). Some have been criticized for having physiologic evaluation data for only a minority of patients treated. In all the studies, however, there was a small but significant improvement in airflow obstruction and a reduction of lung volume. It seems that the bilateral pneumectomy yields improvements in spirometry that are roughly twice as great as these unilateral procedures. In the one available randomized prospective trial of stapled lung reduction versus laser bullectomy surgery (6), patients who received the latter procedure were more likely to develop delayed pneumothorax and less likely to

eliminate dependency on supplemental oxygen. Also, the mean postoperative improvement in the FEV1 at 6 months was greater in those who received the stapled lung reduction technique (32.9% improvement) than the laser treatment (13.4% improvement).

What are the mechanisms of efficacy?

This is an area of controversy and is under active physiologic investigation. Whether Brantigan and Mueller's original theory which suggested that physiologic and clinical improvements were due to improved elastic recoil and efficiency of diaphragmatic and chest wall mechanical function has not been proven. Another untested hypothesis is that improvement occurs due to enhanced right ventricular filling with consequent enhancement of oxygen delivery.

Is the operation safe?

Initial enthusiasm for bilateral reduction surgery was diminished by reports of high morbidity and mortality. Of the centers reporting their results (probably a minority) mortality is varied between 5 and 10%. The most common complication is persistent air leak which may persist for several weeks and is at least 7 days in the majority of patients. Because these patients are often debilitated or have other medical illnesses, surgery has been accompanied by both respiratory and nonrespiratory complications including pneumonia, sepsis, myocardial infarction and stroke. Reported results suggest improved morbidity and mortality of the procedure as the surgeon and center gain more experience.

What is the cost of lung volume reduction surgery?

At the present time the ultimate cost is difficult to gauge as developmental costs and inefficiencies have not yet been eliminated. Estimates of hospital charges range from $35–70,000 per case (exclusive of physician charges and preoperative evaluation). Given the greater than 10 million individuals in this country who have COPD, the cost for individual hospitals and the entire health care system and the impact on funding of other programs could be significant. In view of this, the Health Care Financing Administration (HCFA), which administers the federal insurance program for the elderly, declared that Medicare will no longer pay for lung volume reduction surgery. The agency is currently reevaluating this decision in light of new information.

How should potential candidates for lung volume reduction be evaluated?

As an innovative procedure, the preoperative assessment and criteria for surgery have been evolving and have varied from institution to institution. In general, the patient should have severe emphysema, disabling dyspnea and evidence of severe air trapping. Advanced age (>75 yr) and significant co-morbid illness (cardiac, neurologic, etc.) have been considered contraindications to lung reduction surgery (See Table 1). Extensive preoperative testing may significantly add to the cost but is currently justified by most centers as part of the investigational process.

Who should perform lung volume reduction and where should it be performed?

Given the potential for high morbidity and mortality associated with lung volume reduction, we currently recommend that this procedure be performed by experienced thoracic surgeons in centers where 24-hour cardiopulmonary anesthesia and respiratory care are available. Pulmonary rehabilitation should be mandatory in the pre and post-operative period. The effort should be multidisciplinary and involve respiratory physicians, thoracic surgeons, nurses and respiratory care practitioners. At this point in time, the operation should not be considered experimental, although insufficient data are available to determine if lung volume reduction surgery should be considered standard therapy. Since there are many questions to be answered, we recommend that this operation be performed only at centers where these procedures can be more completely studied through clinical trials and extensive physiologic evaluations. This data should be collected either in a national registry or local registries on every patient who has volume reduction surgery. Controlled clinical trials should be expeditiously organized to establish efficacy.

Conclusions

1) Lung volume reduction surgery appears to be helpful in some, but not all patients with advanced emphysema.

2) Because there are little published data on the indications, patient selection criteria, preoperative assessment, choice of surgical technique and long-term efficacy, further investigation is necessary before definitive recommendations can be made.

3) The conduct of clinical trials, preferably in a controlled, randomized fashion, is urgently needed. At present it is recommended that lung volume reduction surgery be conducted in institutions where a multidisciplinary team including pulmonologists, and thoracic surgeons and a high level of diagnostic and surgical expertise are available. The ATS encourages that surgery be done only on those patients who are part of carefully planned clinical trials with well-defined protocols with outcome measures that will determine the role of lung volume reduction surgery in the future. To achieve this end, it is recommended that funding be provided for multicenter clinical trials.

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[This letter was transcribed from a handwritten letter.]

5818 N.E. 107th Avenue
Vancouver, Washington 98662
April 29, 1997

The Honorable William M. Thomas, Chairman
Ways and Means Health Subcommittee
1136 Longworth House Office Building
Washington, D.C. 20515

Re: Committee hearing on April 17, 1997 (Lung Volume Reduction Surgery)

Dear Mr. Thomas:

The first part of 1996 I was approved to receive the Lung Volume Reduction Surgery at the U.S. Lung Center of Nevada. Just in time to find out that Medicare had stopped approving to pay their part for it. I've called the lung center and they say that other insurances are paying for it. Why am I being punished for having Medicare as my primary insurance? I will always wonder if I had gotten the Lung Volume Reduction Surgery a year ago if I would be able to breathe easier now and wouldn't have to depend on other people doing almost everything for me. Charlotte Nelson of Silverlake, Washington had L.V.R.S. more than a year ago, and I hear she is leading a more comfortable life because of it. It is so scary waking up every night gasping for air. It feels just like someone is choking the life out of me.

Thank you for reading this letter. I hope it will help you to come to the right decision to put Medicare back into L.V.R.S.

Sincerely,

Curtis J. Collins

(by P.R.C. Wife)

Supplemental Statement of Dr. Joel Cooper in Rebuttal to Testimony Presented by Dr. Claude Lenfant

REBUTTAL

I respectfully must disagree with the opinion expressed by Dr. Claude Lenfant that the only means of proving the efficacy of the volume reduction procedure is a randomized clinical trial. A randomized clinical trial is only one of many scientifically valid means of validating a new procedure. It is appropriate, only under limited circumstances, when there clearly is no evidence to support the choice of one treatment over another. In the case of lung volume reduction surgery, numerous articles, technical assessments, and authorities have all concluded that the operation provides benefit which is otherwise not achievable by any other current treatment. What is in question is the duration of the benefit of the procedure, and questions relating to the optimum selection of candidates. These questions do not require randomization but can be answered by offering the operation to appropriate candidates, and carefully collecting and analyzing follow-up data over a period of time.

At a recent meeting of principal investigators for the NIH trial, the head statistician of the clinical coordinating center, chosen by the NIH to supervise the lung volume reduction surgery trial, was asked specifically the question as to whether or not randomization is essential to prove the benefit of the procedure, Specifically, he was asked if comparing post-operative results with pre-operative data in each patient was a valid means of demonstrating efficacy especially as each patient is given optimal medical management before a decision to proceed with surgery is made. We were told that using each patient as their own control was a perfectly valid scientific means of proving the value of the procedure. Furthermore, he noted that if one is looking for a significant improvement following surgery, then a randomized trial is not necessary whereas if one is only looking for small differences between two treatment arms, randomization may be the only way of detecting it.

The lung volume reduction procedure has been demonstrated at numerous centers to produce a very significant functional and physiologic benefit. Therefore, randomization, in my opinion, is not only unnecessary, but is also highly inappropriate for the type of patients who have been shown to derive benefit from the lung volume reduction procedure. Even the recommendation of the AHCPR to HCFA, regarding LVRS, did not call for a randomized trial but for a controlled clinical trial. Offering the operation to appropriate candidates, and carefully measuring and evaluating post-operative results compared to the pre-operative findings represents a controlled trial.

In my opinion there are a group of patients who would be offered the operation under controlled circumstances without rationing or restriction. There is another, even larger group of patients, who do not meet currently accepted criteria for lung volume reduction surgery, yet who might benefit from this operation. For this latter group of patients, it is truly uncertain whether the operation is of value,and randomization between surgical therapy and continued medical therapy would, in my opinion, be scientifically valid and ethically defensible.

In my presentation, I showed a video of a gentleman with severe emphysema before and 2 years after lung volume reduction surgery. The improvement in his breathing and in his overall appearance was striking. I failed to note that this man, though only 58, was so disabled from his emphysema, that he qualified for Medicare, and his life-saving volume reduction procedure was covered by our local Medicare intermediary. Had he not received his operation before HCFA's national declaration of non-coverage, he would almost certainly have died within months.

APRIL 30, 1997

The Honorable William M. Thomas, Chairman
Ways and Means Health Subcommittee

Dear Honorable William M. Thomas:

This letter is a request for your consideration for those who are in need of a "Lung Volume Reduction Operation." This surgery has benefitted hundreds of people suffering from lung disease and hundreds of others can benefit from this procedure with a positive decision from your committee.

I am one of those people waiting to start a productive life style. Why this procedure is annually denied to Medicare patients and has been accepted by private providers. I can't understand thre reasons for delaying governmental approval.

Please take another look at your decision and "Do the Right Thing."

Did I hear you taking a deep breath without thinking about it. Sure feels good huh!

Sincerely,

JIM CUTE
Cape Coral, FL

cc: Senator Connie Mack
Representative Porter Goss

EUGENE DEFAZIO
ANTHONY, FL 32617
April 10, 1997

Congressman William Thomas
Chairman, Subcommittee on Health of the
Committee on Ways and Means

Dear Chairman Thomas:

I am writing this letter to you literally as a matter of life and death, mine. I suffer greatly from severe emphysema. Every single breath I take is a struggle and I am progressively getting worse. I first heard my prognosis in December of 1992, I was then 52. I was told I would get progressively worse with no hope of a cure other than possibly a Lung Transplant. Lung Transplants are a dangerous procedure with high mortality rates due in part to tissue rejection and the fragile nature of lung tissue, finding a suitable donor (someone needs to die in order for you to live) and the cost is in hundreds of thousands of dollars. Needless to say my wife and I were devastated.

We finally had a glimmer of hope in March of 1996, when we heard about Lung Volume Reduction Surgery through our local television station's health report. We were extremely excited but tried not to get our hopes up too high until we found out if I would be a candidate for the surgery. In May of 1996 after completing all the tests required for the doctors to determine if I qualified for surgery, we received the greatest news we have had in our lives since the terrible prognosis, I WAS A CANDIDATE!!! We were so extremely happy and our family and friends were just as elated as us. Then came the bombshell; Medicare (my primary insurance) decided not to cover the surgery anymore deeming the surgery experimental. Our secondary insurance, Blue Cross and Blue Shield, followed suit. To say we were disappointed is an understatement.

I have been fighting for almost a year now for Blue Cross and Blue Shield to pick this up, this is still in appeal, but they are determined to follow Medicare's guidelines even though Blue Cross and Blue Shield Association Medical Advisory Panel has reviewed this surgical procedure and according to Technology Alert dated July, 1996, has determined that performing such surgery by thoracotomy leads to significant improvement in pulmonary function, dyspnea, and functional well being and meets the Blue's Technology Evaluation Centers criteria for determining that a treatment is effective.

How can Medicare not pay for this surgery? How can they pay for it and suddenly decide not to? This is my only hope Chairman Thomas, as it is a LIFESAVING procedure for me that not only will improve the quality of my life but will also save me from numerous hospital stays and a lot of pain and suffering; which is inevitable with the progression of this disease. I am sure you would not like to die this way and I do not want to either. I would not have to if Medicare paid for this procedure.

Please help get Medicare to again pay for this Life Saving surgery, not only for myself but for everyone who suffers from this horrible disease.

Thank you for letting me have a voice and I appreciate greatly your attention to this matter.

Very truly yours,

EUGENE DEFAZIO

ED:msd

cc: Anne Van Waes, M.S., R.N., Program Coordinator, U.S. Lung Center Washington Adventist Hospital

BENJAMIN A. GILMAN
20TH DISTRICT, NEW YORK

INTERNATIONAL RELATIONS COMMITTEE
CHAIRMAN

SUBCOMMITTEE:
INTERNATIONAL OPERATIONS AND HUMAN RIGHTS

GOVERNMENT REFORM AND OVERSIGHT COMMITTEE

SUBCOMMITTEES:
POSTAL SERVICE
CIVIL SERVICE

Congress of the United States
House of Representatives
Washington, DC 20515–3220

Remarks -- Rep. Benjamin A. Gilman
April 17, 1997
Lung Volume Reduction Surgery

I want to thank Chairman Thomas for agreeing to hold a hearing to focus in on Medicare coverage policy and its adverse impact on coverage and reimbursement for lung volume reduction surgery (LVRS).

As you know, Congress required that HCFA study all of the data available regarding LVRS and report its findings by January 1st of this year along with recommendations as to when it will restore Medicare reimbursement for this important procedure. This action was taken by Congress due to its discontent with HCFAs decision not to extend Medicare coverage to LVRS. However, it is becoming apparent that HCFA is not taking this congressional mandate seriously.

In fact, while HCFA over the past 30 years have approved state-of-the-art health care technology and procedures, including ventricular assist devices to provide a bridge to a transplant for Medicare beneficiaries, it has failed to take adequate action on LVRS, and has concluded that LVRS should only be covered by Medicare in the context of a controlled study.

HCFAs decision to continue its non-coverage policy is based upon the health care technology assessment which they requested from a 1996 Agency for Health Care Policy and Research (AHCPR) study, which was based both limited data and experience than is now available. Moreover, if the AHCPR report had separated out the data from different procedures, as is now required by federal law, LVRS results would be more favorable. Finally, the report concluded that some patients have received benefits from LVRS, and thus "if the surgery could be accomplished without undue morbidity or mortality, a prospective trial of LVRS under uniform protocol requirements with comprehensive long term postoperative follow-up data is both ethically supportable and scientifically essential."

Mr. Chairman, it is interesting to note that AHCPRs assessment did not recommend, as HCFA has, that access to the procedure be limited or that randomization be imposed as a prerequisite for LVRS access. Furthermore, as the Subcommittee knows, HCFA has plenty of experience managing a controlled study through registries without randomization. Accordingly, it is obvious to me, and at some concern, that HCFA is recommending randomization to limit the cost of LVRS reimbursement to HCFA. Rationing health care through randomization limits the number of eligible patients who actually receive Medicare reimbursed LVRS, and will create the false notion that the procedure has not yet demonstrated a proven benefit.

PLEASE REPLY TO:

☒ WASHINGTON OFFICE:
2449 RAYBURN BUILDING
WASHINGTON, DC 20515–3220
TELEPHONE: (202) 225–3776

☐ DISTRICT OFFICE:
407 EAST MAIN STREET
SUITE 2
P.O. BOX 358
MIDDLETOWN, NY 10940–0358
TELEPHONE: (914) 343–6666

☐ DISTRICT OFFICE:
377 ROUTE 59
MONSEY, NY 10952–3498
TELEPHONE: (914) 357–8000

☐ DISTRICT OFFICE:
32 MAIN STREET
HASTINGS-ON-HUDSON,
NY 10706–1602
TELEPHONE: (914) 478–5550

Accordingly, Mr. chairman, I support the following three recommendations to eliminate the rationing of health care through an unethical and discriminatory HCFA study:

[1] Replace the study with a national registry;

[2] Permit patients who meet the appropriate patient selection criteria developed through surgical experience to have LVRS which would be reimbursed through HCFA; and

[3] Permit those medical centers that meet appropriate participation criteria to provide LVRS to patients and get reimburse by HCFA.

Again, I thank you, Mr. Chairman, for holding these hearings and look forward to working with you on this important issue.

ELIZABETH JEAN JACKSON
ANDOVER, NEW YORK 14806
April 14, 1997

Congressman William Thomas
Chairman, Subcommittee on Health of the
Committee on Ways and Means

A.L. Singleton, Chief of Staff
Committee on Ways and Means
U.S. House of Representatives
1102 Longworth House Office Bldg.
Washington, D.C. 20515

Re: Subcommittee on Medicare's Coverage Policy: Lung Volume Reduction Surgery

My name is ELIZABETH JACKSON, a retired nurse who had suffered from the effects of emphysema for many years, until I had to retire in 1988. My condition worsened until I was told by my doctor that nothing more could be done for me, other than to be given oxygen and inhalation therapy, which might allow me to live a little longer, something I really didn't care to do. But thanks be to GOD and to my son, who wouldn't accept the fact that nothing could be done, I am now a vital human being once more, enjoying every minute of my life and breathing normally, doing my own housework, and find myself so busy there isn't even time to take a vacation.

I am very thankful that hearings are about to begin concerning funding for the lifesaving procedure known as Lung Reduction Surgery with Laser Plication. It is a procedure which allows a patient to take back control of their life and breathe normally again. As it is now, only those who are fortunate enough to have their own hospitalization insurance or are able to mortgage their homes can even hope to have this procedure done. This excludes the vast majority of persons who suffer from this most debilitating, life-threatening disease.

I wish there was a way to demonstrate what it actually feels like to suffer from the effects of emphysema. Perhaps if you pinched the end of your nose until very little air could be taken in, it would give you an idea of what a person with this disease goes through every waking moment, not to mention the danger one faces when trying to sleep, due to sleep apnea. The everyday medical costs, oxygen inhalation therapies and frequent hospitalizations are other factors that make this disease so devastating. Even a common cold always sees to turn into pneumonia, making it difficult to be around those who might be coming down with one, further isolating one from normal social contact. This often causes a deeper depression that one has anyway from being sapped of all energy and still living on and feeling one is a burden to their family.

Before I had surgery I was confined to my home, unable to shop for myself or do my own housework. I was on oxygen at 4 liters around the clock and inhalation therapy. I was so very depressed and felt I was a burden, even though my family never complained about the extra work piled onto them. A year or so before I retired from my job as primary care nurse at our local hospital, I had to ask our director not to make me "code nurse," because I was unable to run to the E.R. whenever a code came in. They granted this request and I continued working until I was so exhausted it took me a couple of days to recuperate from one busy night's work. My son called the American Lung Association in the fall of 1995 to see if there was anything new being done in the treatment of emphysema, and that's when we called U.S. Lung Centers, they sent us the information we needed, and the rest is history!

I underwent surgery last April. Seventeen days later, I came home and three days after that I was singing in our church choir. I came home with only a mild pain reliever, which I took for a few weeks. I was told to keep my oxygen until the doctors were sure I didn't need it, and can only remember using twice after returning home, and then it was just for a few minutes. I am now without O_2 or any inhalers. I take no medication whatsoever. My life is so busy, joyful, and I am so thankful to be a useful person again. I was very lucky that my disease hadn't progressed to heart failure yet and that I had no other existing health problems, which made me a good candidate for this surgery. There are many others out there who could be enjoying a productive life, if only they had a chance. It would seem to me it would be cheaper for Medicare to pay for surgery rather than spend millions on oxygen

and hospital costs of the chronically disabled emphysema patient for years and years.

Please sir, I hope you will seriously consider helping all people with this dire problem. Please don't allow them to be singled out as not being worth saving. Talk to those who have been lucky enough to obtain this operation. They'll tell you how great it is to breathe again normally, something that you may just be taking for granted.

Thank you so much for conducting these hearings. May they bring to fruition the hope of emphysema patients everywhere.

Sincerely,

ELIZABETH JEAN JACKSON

ALFRED MUNZER
PULMONARY MEDICINE
WASHINGTON ADVENTIST HOSPITAL
TAKOMA PARK, MD 20912

April 30, 1997

Congressman William Thomas
Chairman, Subcommittee on Health
Committee on Ways and Means

A.L. Singleton, Chief of Staff
Committee on Ways and Means
U.S. House of Representatives
1102 Longworth House Office Building
Washington, D.C. 20515

Mr. Chairman and Members of the Subcommittee:

I am a physician specializing in lung disease and co-director of the Department of Pulmonary Medicine at Washington Adventist Hospital in Takoma Park, MD. I am also a past-president of the American Lung Association, but submit these comments on my own behalf and on behalf of the thousands of patients with emphysema who are likely to benefit from lung volume reduction surgery, but who are currently denied access to this mode of therapy by the Health Care Finance Administration.

I was very skeptical of the early reports on the benefits of lung volume reduction surgery, but am now convinced by an ever increasing body of clinical and experimental evidence that removing the most diseased parts of the emphysematous lung allows the remaining part to gain elasticity which translates into better function of the lung and chest wall muscles and therefore into an decrease in breathlessness and an increase in exercise tolerance. More importantly, however, I have now personally witnessed a marked improvement in the lung function and well-being of my own patients who have undergone the surgery.

I wholeheartedly agree with the position espoused by the American Thoracic Society, the medical arm of the American Lung Association, that more studies are needed to establish sound criteria for the selection of candidates for lung volume reduction surgery. But that need does not relieve the Health Care Finance Administration from its mandate to extend the benefits of a new mode of therapy that is broadly accepted by the medical community and that has been proven to be effective in the peer reviewed scientific literature, to Medicare recipients.

In its present stance, the Health Care Finance Administration runs the risk of repeating the sad chapter of the Tuskegee experiments of fifty years ago.

Sincerely,

ALFRED MUNZER, M.D.

IVAN J. WEAVER
3171 MARIETTA AVENUE
LANCASTER, PA 17601
April 14, 1997

Congressman William Thomas
Chairman, Subcommittee on Health of the
Committee on Ways and Means

Dear Representative Thomas:

I have been an emphysema patient for more than twelve years. Experiencing shortness of breath for a period of time, I contacted my physician and after a chest x-ray, I was diagnosed as having emphysema. At that time, my physician gave me a list of breathing exercises as well as other types of exercises and told me to refrain from using tobacco and alcohol and to try to keep what breathing capacity I had. This I did faithfully, and I still do. However, I learned, over a period of time, that keeping the capacity I had was not possible. I do, however, believe that doing those exercises plus a lot of walking is the reason I have survived to this day.

As time passed by, I gradually lost my battle with the disease. By September, 1995, I had to rely on oxygen continually and became, for the most part, a wheelchair patient. I never stopped exercising and walking, even though it became very difficult and less frequent than the daily routine which I followed for so long a period of time.

At this juncture, we contacted the University of Pennsylvania Hospital, Philadelphia, PA, regarding the possibility of Lung Volume Reduction Surgery. Supplying them with the necessary tests, which they requested, we were then directed to come to their institution for further testing and evaluation. Upon completion of these tests, which required several trips to the above mentioned institution, I was declared a candidate for surgery and the date was set. This all happened by mid December, 1995. The surgery date was set for February 12, 1996.

On February 3, 1996, the local newspaper carried a story about Medicare cutting coverage for Lung Volume Reduction Surgery. This was the first indication of this nature. On Monday, February 5, 1996, I called the University of Pennsylvania Hospital and was told they knew nothing of it and my surgery date remained as scheduled. Only to be called four days later, February 9, 1996, and told the surgery was cancelled and at the same time the program at the hospital was cancelled. I was totally DEVASTATED!

The weeks that followed were spent pleading our case with HCFA, but to no avail. As a matter of fact, with complete indifference. It became evident that another approach was necessary, because the projected seven year evaluation was simply too long to wait. I was running out of time.

At this time, I believe that Divine Intervention took place. A family member discovered a small advertisement in a magazine where it said U.S. Lung Centers had a program to provide Lung Volume Reduction Surgery in Anaheim, California. Upon contacting them, they referred me to their closest affiliate, The Washington Adventist Hospital, 7600 Carroll Avenue, Takoma Park, MD 20912. Getting in contact with them, they requested and received a copy of all previous testing, where upon, they had us spend three days at their hospital for their testing and evaluation, which we found to be very thorough.

Three weeks later, surgery was scheduled and performed. In the meantime, I mortgaged my home to pay for the surgery.

The professional level was second to none. There were no surprises after surgery as I was informed of everything, step by step, beforehand, as well as meeting personally with everyone who would be connected with my rehabilitation. All contacts and visitations at the hospital were taken care of by Anne Van Waes, who happens to be the program coordinator. Anne leaves no stone unturned.

Since my surgery, I have had periodic visits and on April 24, 1997, I'm scheduled for my six month visit, which I am looking forward to. My quality of life has improved immensely and I am able to walk short distances, go shopping, go to the barber shop, to the bank, etc. without oxygen. I am looking forward to taking my 5 year old grandson fishing, something I would have never been able to even consider doing prior to my surgery.

I do daily exercises with oxygen, and I look and feel so much better. I thank God for the Washington Adventist Hospital and their staff. I would certainly hope they can be a part of any program of the future.

Sincerely,

IVAN J. WEAVER

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